PREVENTING RECURRENT ANKLE SPRAINS

THE IMPLEMENTATION EFFECTIVENESS OF THE ‘STRENGTHEN YOUR ANKLE’ APP

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The studies presented in this PhD thesis were conducted within the Amsterdam Collaboration on Health & Safety in Sports and the Amsterdam Public Health Research Institute, at the Department of Public & Occupational Health of the Amsterdam University Medical Center, location VUmc, the Netherlands.

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CHAPTER 1
General introduction
A minor injury?

We exercise for the love of sport, for keeping fit, for losing weight or because we enjoy spending time with friends. Whatever the reason, there is no discussion that regular exercise benefits our health: both physically and mentally [1]. One could argue that the only disadvantage of being physically active is the risk of getting injured [2]. While exercise is generally advocated to contribute to overall well-being, it comes with a health risk, both for the individual, as for society as a whole [2]. That this risk is substantial is clearly illustrated by the following: the Dutch OBiN research (ongevallen en beweging in Nederland: accidents and exercise in the Netherlands) calculated that the Netherlands has a population participating in sport of just over 12 million. These 12 million people were confronted with no less than 4.5 million injuries in 2013 only; 3.2 Million (69%) of those injuries was classified as acute, and 1.9 million injuries (42%) was medically treated. The body parts that are most often affected by an injury are the knee and the ankle, with respectively 970.000 and 680.000 injuries. The single most common injury is an ankle sprain [3], which makes up 85% of all ankle injuries (480.000). A previous cost-effectiveness study [4] has shown that, disregarding the requirement of medical treatment, the mean total (direct and indirect) cost of one ankle sprain amounts to approximately €360. This gives a rough estimate of the annual (201C) sports related ankle sprain costs in the Netherlands of €183.6M. In addition to societal costs, there is extensive evidence that there is an up to twofold increased risk for ankle re-injury during the first-year post-injury [5,6]. In about 50% of all cases recurrences may result in disability, can lead to chronic pain or instability and may require prolonged medical care [5]. As such, ankle sprains pose a significant burden to the individual athlete and to society.

An efficacious solution at hand

Previous research has shown that both externally applied ankle supports (i.e. taping or bracing), as well as neuromuscular training programs are successful in preventing recurrent cases of ankle sprain, both from an effectiveness, as well as a cost-effectiveness perspective [7,8,9]. While such measures have not been linked to a primary preventive effect, these measures can reduce the increased risk of recurrent injury to the same level as never injured athletes. Therefore, in most current treatment guidelines, secondary preventive measures - preferably through continued neuromuscular training - are recommended after rehabilitation. Not only have these secondary preventive efforts shown to be efficacious, they are also associated with high short-term (i.e. 1 year) returns on investment. The neuromuscular program that is the centre of this thesis has been linked to a €100 net return for each intervention package handed out [8]. The ‘Versterk je Enkel’ neuromuscular training program consists of six exercises taking all together eighteen minutes, that should be performed three times a week over an eight-week period. With the use of a detailed schedule the user is challenged to increase the difficulty of the program over time.
Efficacious but without effect

Although this program has been shown to be effective in reducing recurrent ankle sprains, large-scale community uptake of the preventive measure is lagging behind. This is despite the high prevalence of ankle sprains, and despite an active stand by various Dutch stakeholders – such as sports federations, general practitioners, physiotherapists and the National Olympic Committee - in implementing the neuromuscular training program. The lack of widespread uptake, results in the fact that ankle sprains continue to make up a large percentage of all sport injuries. The Dutch injury rates, registered by the Dutch Consumer Safety Institute VeiligheidNL [3], showed that ankle sprain rates have been consistent over the past years.

While the neuromuscular program has been proven (cost-)effective [8,9] compliance with the program is poor [9]. In fact, the preventive effect in these studies was achieved only in a subsample of compliant participants showing significant population effects. However, analyses were done from an intention-to-treat approach, implying that there is much to gain at both an individual as a population level by increasing compliance.

A contemporary approach to the problem?

It has been increasingly acknowledged that preventive interventions should not only be based on evidence-based medicine but should include also user’s opinions and barriers [15, 16]. In this thesis, the study population varied from elite athletes aiming for top performance to elderly people whose main aim was to continue their activities of daily living without difficulties. Interventions for such a diverse population should be suited for all those involved. In previous studies from this research group it was concluded that, although the program was effective, methods of implementation should be improved to end up with an intervention with the lowest barriers possible to everyday use [2].

In an attempt to bridge this so-called implementation gap, VeiligheidNL looked into the possible feasibility of new (social) media in injury prevention. A freely available interactive App ('Versterk je Enkel'; available for iOS and Android) was developed that contains - next to general advice on bracing and taping - the cost- effective neuromuscular training program previously developed by this research group. It is generally assumed that such interactive, online and mobile methods of information transfer are the way forward in prevention and implementation efforts. However, this has not yet been formally established for the uptake of evidence-based injury preventive measures. While numerous mobile apps are available, only few contain prevention advice that is actually supported by scientific evidence [17]. Furthermore, although user reviews are positive - the 'Versterk je Enkel' App has not been evaluated against the well-studied ‘regular’ approach to advocate the neuromuscular training program by making use of printed and DVD materials. If the ‘Versterk je Enkel’ App indeed does increase intervention uptake, this will provide the necessary validation to further develop and enhance this promising role of new media in the implementation of preventive measures and interventions.
The outline of this thesis

The aim of this thesis was to evaluate the implementation value of the ‘Versterk je Enkel’ App as compared to the usual practice of providing injured athletes with ‘ordinary’ materials. The premise was that use of the ‘Versterk je Enkel’ App would increase compliance to the prescribed program and, consequently, would decrease ankle sprain recurrence incidence.

Chapter 2 contains the study design article that was published during initiation of the current study.

In chapter 3 one can find a review study in which the main features of 100 RCTs are described that deal with sport injury prevention. The main topic of concerned ‘how sport injury studies deal with the concept of compliance’. It was also looked at how compliance was defined, measured and reported and what effect compliance rates had on the effectiveness of preventive interventions.

Chapter 4 The study presented in this chapter evaluated whether the ‘Versterk je Enkel’ application resulted in in a higher compliance to the to the embedded prescribed 8-week exercise program, and whether there was a difference in program effectiveness between groups of users that had used the program in its original paper form, versus an interactive app form.

Chapter 5 reports the long-term study results of a 12-month follow-up during which the neuromuscular training program was no longer continued. During these 12 months, recurrent injuries in the study population were analysed by monthly online questionnaires. The main question of this chapter was if there was a difference in ankle sprain recurrence incidence rates between the group applying the ‘Versterk je Enkel’ App or the group using written materials.

In chapter 6 a study is described in which the cost-benefit of the intervention was analysed. This chapter focused on two questions. Firstly, is there a difference in direct and indirect costs during a 12-month follow-up, between groups applying the ‘Versterk je Enkel’ App and written materials? And secondly, is there a difference in ankle sprain residual complaints (i.e. instability, feeling of giving way, pain, and continued sports participation) after a 12-month follow-up, between groups applying the ‘Versterk je Enkel’ App and written materials? This chapter gives insight in the cost-effectiveness of the intervention as compared to usual care.

Chapter 7 presents a qualitative evaluation of the neuromuscular training program which is based on semi-structured interviews and open questionnaires. By means of the interviews and open questionnaires, the barriers and facilitators that affected program compliance were evaluated. In addition, the subjective user experience of the ‘Versterk je Enkel’ App and the written materials was examined.

Finally, in chapter 8 the general discussion presents an overview of the main results, discusses methodological issues and provides suggestions for future research.
REFERENCES


CHAPTER 2
The implementation effectiveness of the ‘Strengthen your ankle’ smartphone application for the prevention of ankle sprains: design of a randomized controlled trial

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ABSTRACT

Ankle sprains continue to pose a significant burden to the individual athlete, as well as to society as a whole. However, despite ankle sprains being the single most common sports injury and despite an active approach by various Dutch organisations in implementing preventive measures, large-scale community uptake of these preventive measures, and thus actual prevention of ankle sprains, is lagging well behind.

In an attempt to bridge this implementation gap, the Dutch Consumer Safety Institute VeiligheidNL developed a freely available interactive App (‘Strengthen your ankle’ translated in Dutch as: ‘Versterk je enkel’; available for iOS and Android) that contains next to general advice on bracing and taping - a proven cost-effective neuromuscular program. The ‘Strengthen your ankle’ App has not been evaluated against the ‘regular’ prevention approach in which the neuromuscular program is advocated through written material. The aim of the current project is to evaluate the implementation value of the ‘Strengthen your ankle’ App as compared to the usual practice of providing injured athletes with written materials. In addition, as a secondary outcome measure, the cost-effectiveness will be assessed against usual practice.

The proposed study will be a randomised controlled trial. After stratification for medical caregiver, athletes will be randomised to two study groups. One group will receive a standardized eight-week proprioceptive training program [10,11] that has proven to be cost-effective to prevent recurrent ankle injuries, consisting of a balance board (machU/MSG Europe BVBA), and a traditional instructional booklet. The other group will receive the same exercise program and balance board. However, for this group the instructional booklet is exchanged by the interactive ‘Strengthen your ankle’ App.

This trial is the first randomized controlled trial to study the implementation effectiveness of an App for proprioceptive balance board training program in comparison to a traditional printed instruction booklet, with the recurrence of ankle sprains among athletes as study outcome. Results of this study could possibly lead to changes in practical guidelines on the treatment of ankle sprains and in the use of mobile applications for injury prevention. Results will become available in 2014.

Keywords: Mobile health, Ankle sprains, Ankle injury, Prevention, Neuromuscular training

Trial registration

The Netherlands National Trial Register NTR 4027. The NTR is part of the WHO Primary Registries.
BACKGROUND

Ankle sprains are the most common sports and physical activity (PA) related injury [1-3]. It has been estimated that approximately 25% of all injuries across all sports are ankle injuries. Of all ankle injuries 85% involve the lateral ankle ligaments, i.e. acute lateral ankle sprains [3]. In the Netherlands, the most recent count of sports injuries showed that there is an estimated absolute number of 3.7M acute sports injuries each year in a sporting population of 11M athletes [4]. Of all annual sports injuries, approximately 530,000 are ankle sprains, of which almost 40 per cent requires (para)medical treatment [5]. Our research group has previously shown in a cost-effectiveness study [6] that, disregarding the requirement of medical treatment, the mean total (direct and indirect) cost of one ankle sprain is approximately €360. This would give a rough estimate of the annual sports-related ankle sprain costs in the Netherlands of €190,800,000. In addition, there is extensive evidence that there is an up to twofold-increased risk for ankle re-injury during the first year post-injury [6,7]. In fifty percent of all cases recurrences may result in disability and can lead to chronic pain or instability, requiring prolonged medical care [8]. As such, ankle sprains continue to pose a significant burden to the individual athlete, as well as to society as a whole.

Research has shown that both externally applied supports (i.e. taping or bracing of the ankle), as well as neuromuscular training programs are very successful in preventing recurrent ankle sprains, both from effectiveness, as a cost-effectiveness perspective [3,9,10]. While such measures have not been clearly linked to a primary preventive effect, the increased risk of recurrent injury can be reduced to the same level as previously uninjured athletes.

Therefore, in all current ruling treatment guidelines secondary preventive measures - preferably through continued neuromuscular training - are recommended after rehabilitation. These secondary preventive efforts regarding ankle sprains have been associated with high short-term returns on investment. The neuromuscular program that will be the centre of the proposed project, has been linked to a €100 net return for each intervention package distributed [10].

However, despite ankle sprains being the single most common sports injury and despite an active approach by various Dutch organizations in implementing effective preventive measures and interventions, large-scale community uptake of preventive measures, and thus actual prevention of ankle sprains, is lagging well behind. This challenge can be derived from the Dutch injury rates registered by the Dutch Consumer Safety Institute VeiligheidNL [5], indicating that ankle sprain rates, treated at hospitals’ Emergency Departments, are consistent over the past years. In addition, the previously mentioned neuromuscular training program, that has been proven effective [8] and cost-beneficial [6], has been shown to have poor compliance [12]. In fact, the preventive effect in former studies was achieved in a subsample of compliant athletes, nevertheless showing significant population effects. Although analyses have been done from an intention-to-treat approach, this shows there is a lot to gain at an individual as well as a population level by increasing compliance to these simple and effective measures that are being advocated in various treatment guidelines.
In an attempt to bridge this implementation gap, VeiligheidNL looked into the possible role of new (social) media and has developed a freely available interactive ‘Strengthen your ankle’ App; available for iOS and Android) that contains next to general advice on bracing and taping - the cost-effective neuromuscular program, as evaluated in a previous trial. This App provides the user with videos and an interactive neuromuscular exercise schedule. It is a general belief that such interactive, online and mobile methods of information transfer are the way forward in prevention and implementation efforts. However, this has not yet been formally established for the uptake of injury preventive measures, and - although user reviews are positive - the ‘Strengthen your ankle’ App has not been evaluated against the well-studied ‘regular’ approach to advocate the neuromuscular program through written materials. Furthermore, if the ‘Strengthen your ankle’ App indeed does increase intervention uptake this will provide the necessary validation to further develop and enhance this promising role of new media in the implementation of preventive measures and interventions.

**OBJECTIVES**

The objective of this randomised controlled trial is to evaluate the implementation value of the 'Strengthen your ankle' App as compared to the usual common practice of providing injured athletes with written materials.

Our hypothesis is that the use of the ‘Strengthen your ankle’ App will increase compliance to the prescribed neuromuscular training program and, consequently, will decrease ankle sprain recurrence incidence.

Specific research questions that will be answered are:

- What is the compliance to the prescribed 8-week exercise program via the App and via written material?
- Is there a difference in program compliance rates between the ‘Strengthen your ankle’ App and written materials?
- Is there a difference in ankle sprain recurrence incidence rates during a 12-month follow-up, between groups applying the ‘Strengthen your ankle’ App and written materials?
- Is there a difference in direct and indirect costs during a 12-month follow-up, between groups applying the ‘Strengthen your ankle’ App and written materials?
- Is there a difference in ankle sprain residual complaints (i.e. instability, feeling of giving way, pain, and continued sports participation) after a 12-month follow-up, between groups applying the ‘Strengthen your ankle’ App and written materials?
- What is the participants’ user experience of the ‘Strengthen your ankle’ App and the written materials?
METHODS

Design

The proposed study will be a randomised controlled trial. The study design and flow of the athletes are shown in Figure 1. The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee (no. 2013/248) of the VU University Medical Center Amsterdam (VUmc), the Netherlands. The trial is registered in the Netherlands Trial Registry (NTR4027).

Participants

Active participants (athletes), between 18 and 70 years of age, who have sustained an ankle sprain within the past two months, are eligible for inclusion. Responders are excluded if they have suffered from an injury different from a lateral ankle sprain in the same ankle (e.g. fracture of the ankle) in the previous year. Athletes should own a mobile phone with either Android or iOS. Athletes will be recruited through participating caregiving practices, websites from national sport federations, newsletters, an open invitation via the Internet and through the communication channels of participating sport associations.

STUDY OUTLINE

Randomisation procedure

After athletes have finished ankle sprain treatment by means of usual care, they will be randomised to one of the two study groups with stratification for initial treatment (i.e. medical or non-medical). Randomisation will take place at the end of treatment. This will minimise the risk of allocation bias. In addition, this will provide room to contact the medical care provider(s) involved in the athletes’ treatment. Medical care providers will be informed about the study in which the athlete partakes and will be asked to follow their usual treatment and/or rehabilitation program. Furthermore, they will be asked to encourage the athlete to take up their allocated intervention program after treatment and/or rehabilitation has ceased.

Athletes allocated to the ‘regular’ intervention group will receive a standardized eight-week proprioceptive training program, consisting of a balance board (machU/ MSG Europe BVBA), and an instructional booklet. This program has been shown to be effective in reducing recurrence injury risk in previous randomized controlled studies [9,10].

Athletes allocated to the ‘App’ group will also receive a balance board (machU/ MSG Europe BVBA), but the standardized eight-week proprioceptive training program will be provided through an interactive smartphone application, which is freely available for Android and iOS users. These two platforms are the most commonly used operating systems on smartphones (of all smartphones 79,3% runs on android, 13,2% on iOS) (18). Thereby, selection bias is considered minimal. All athletes receive the same balance board. Both the instruction booklet and the ‘Strengthen your ankle’ App contain the same training program and six basic exercises (Figure 2).
Figure 1 Study design and flow of the athletes


Figure 2 Basic exercises of the ‘Strengthen your ankle’ proprioceptive training program.

**Baseline measurement**

The online baseline questionnaire gathers information of each athlete on demographic variables, physical characteristics, sports & injury history, use of preventive measures, knowledge on injury prevention, severity of the current ankle sprain and subsequent treatment and/or rehabilitation.

**Follow-up measurement**

After the 8-week training program, athletes will receive an online follow-up questionnaire to measure residual complaints of the initial ankle sprain and attitude towards the prescribed exercises. Both pain and feeling of giving way will be scored on five-point Likert scale for a series of questions.
Recurrent injury incidence and cost of injury outcomes will be measured once a month for a total period of 12 months. The follow-up measurements will gather information for each athlete on ankle sprains sustained during the preceding month, including details and mechanisms of this sprain and absence from sports due to the ankle sprain recurrence as a measure of recurrence severity. Finally, these online follow-up questionnaires will measure residual complaints of the initial ankle sprain. Both pain and feeling of giving way will be scored on five-point Likert scale for a series of questions, e.g. do you feel pain when being active, do you feel pain when getting out of bed in the morning, do you feel your ankle giving way when walking across the street, etc. At the last follow-up measurement (12 months) residual complaints of the initial ankle sprain will be measured again in all athletes.

**Compliance**

Compliance (primary outcome) measurements will commence after randomisation (i.e. after treatment and at the start of the allocated intervention) and will take place weekly for the duration of the program (8 weeks). These measurements will gather information for each athlete on the number and sets of executed exercises. In addition, online questions will be asked regarding the clarity of the instructions provided, difficulty of the exercises and recurrence of an ankle sprain.

**Cost diary**

In order to evaluate the cost-effectiveness of the allocated interventions, athletes who sustain an ankle sprain recurrence will be contacted by phone to obtain information on costs associated with treatment. Based on this information direct and indirect costs resulting from the sustained ankle sprain recurrence will be calculated for use in an economic evaluation. The economic evaluation will be performed from a societal perspective.

**Cost-effectiveness evaluation**

Costs of the allocated intervention will include costs that are directly related to the implementation of the allocated intervention program. These costs include the written information materials, the development and maintenance of the application, and the balance boards. In addition to the cost of the intervention itself, direct health care costs will be included, i.e. costs of care by a general practitioner, physiotherapist, massage therapist, alternative therapist, sports physician or medical specialist (e.g., orthopaedic surgeon, general surgeon); hospital care, use of drugs (e.g. acetaminophen, ibuprofen) and the use of medical devices (e.g., crutches, tape, braces). The costs of drugs will be estimated on the basis of prices recommended by the Royal Dutch Society of Pharmacy (19). Also, indirect costs resulting from a loss of production due to absenteeism from paid or unpaid work will be included. Indirect costs for absenteeism from paid work are calculated using the friction cost approach of 4 months, based on the mean age and sex specific income of the Dutch
population. Indirect costs for productivity loss of unpaid work, such as study and household work, costs are estimated at a shadow price of € 8.30 an hour (20).

Sample size

Sample size calculations are based upon the primary outcome measure compliance, and are based upon previously established compliance rates to the same program when advocated through written materials [12]. Full compliance rates in the written materials’ group are expected to be around 25%. A doubling of this rate to at least 50% is considered to be clinically relevant. Based upon a beta of 0.90 and an alpha of 0.05 a total of 158 athletes is required divided across both study groups. In our experience from previous comparable studies the dropout rate during a 12 months follow-up is about 20%. This would mean that a sample of 190 athletes is needed per group.

Recruitment of study population

Physical therapy and physician practices will aid in the recruitment of athletes. Participating practices will be instructed on the aim, background and procedures of the study. Athletes treated for an ankle sprain at participating practices will be informed of the study by their caregiver. Athletes willing to participate, will then be contacted by the research team by phone after which they will enrol in the study.

Athletes will also be recruited through the Internet. Calls will be placed on the websites of associations of sports with a relatively high ankle sprain rate (volleyball, handball, basketball, korfbal, soccer and athletics), websites of organisations participating in this study and on sports-related websites (e.g. www.meetingpoint.nl, www.runinfo.nl, www.volleybalforum.nl, etc.). Where possible, existing mailing lists of sport associations will be used to contact potential athletes directly. In addition, electronic newsletters will be used for active recruitment of athletes.

The same recruitment strategy as described above has been employed successfully in two previous studies on the same topic [13,14]. In both studies a larger sample of injured athletes was successfully included, 476 and 352 athletes respectively.

One of the drawbacks of this method of inclusion is that we have no control over the treatment that is being given or has been given for the current ankle sprain. Although ruling guidelines are considered usual care, this does not necessarily mean that caregivers are actually following these guidelines by the book. Inclusion of athletes through a limited number of controlled (para)medical caregivers would decrease this problem. However, as we have learned in previous studies, inclusion through such channels is problematic and almost always results in lower inclusion rates than expected. Even so, in the proposed study we are looking for athletes treated by a variety of (para)medical caregivers. Meaning that in the proposed study a relatively large number of different caregivers would need to be found, informed on the study, and controlled as to their given treatment. Looking at the required number of athletes we believe this would prove an undoable and unrealistic
undertaking. Moreover, the proposed study is on the effect of secondary preventive measures that are being applied after treatment by the (para)medical caregiver. When the caregiver would perform inclusion, this means that randomisation needs to take place at the level of the caregiver. This further complicates the study design.

**Usual care as employed in the current study**

For the current study, usual care is defined as any care the athlete might seek or receive after an ankle sprain. We also define self-treatment to be usual care in the current study. Next to treatment by a (para)medical professional 60 per cent of ankle sprains - mostly minor - is self-treated by the athlete (5). Consequently, these athletes do not receive the care as described in the below mentioned ruling guidelines.

In case the athlete does receive (para)medical care, there are two ruling medical guidelines for the treatment of ankle sprains in the Netherlands, i.e. the Royal Dutch Physiotherapy Association (KNGF) guideline (16) and the Dutch Institute for Healthcare Improvement (CBO) guideline (17). The KNGF guideline, which is the most commonly employed, aims at optimal functional recovery of the ankle, returning to full sports participation and preventing recurrent ankle injuries. Rehabilitation consists of three phases: phase 1 which aims to reduce pain and swelling, phase 2 in which load is gradually increased and functionality is re-established and phase 3 in which normal average daily living (ADL) tasks are performed. After full rehabilitation athletes are advised to use secondary preventive measures. Whereas elite athletes could have treatment duration of up to twelve weeks, six weeks are considered sufficient for amateur athletes, according to the KNGF guidelines (16).

For the purpose of the current study we do not interfere in the athletes’ choice of caregiver and the caregivers’ compliance to the ruling guidelines.

**Statistical analyses**

All analyses will be carried out according to the intention-to-treat principle.

Compliance rates between groups will be compared by means of a multivariate linear regression analysis using compliance as a continuous dependent variable. Cox-regression analysis will be used to compare ankle recurrence risk between the intervention and the control group. Absence from sports will be compared between the two groups using a Mann-Whitney test, since absence from sports due to an injury is not normally distributed. For all analyses, variables will be checked for confounding and/or effect-modification and will be adjusted for accordingly.

Mean direct, mean indirect and total costs will be estimated and compared between the two groups, both for the costs per athlete in the injured population and for the costs per athlete in the total population. Because costs will not be normally distributed, 95% confidence intervals for the differences in mean costs will be obtained by bias-corrected and accelerated bootstrapping with 2000 replications. Differences in costs and differences
in ankle sprain recurrences will be included in a cost-effectiveness ratio, which estimates the incremental costs to prevent one ankle sprain recurrence. Confidence intervals for the cost-effectiveness ratio will be calculated with bootstrapping, using the bias-corrected percentile method with 5000 replications. Uncertainty of this ratio will be evaluated by presenting a cost-effectiveness plane and sensitivity analyses will be performed to check the robustness of the results. An acceptability curve will also be presented.

**Impact of results**

The results of this study can possibly lead to a change in the treatment of ankle sprains. Positive results can offer extended possibilities for implementation of the intervention in usual care. Positive study results can also lead to changes in the practical guidelines on the treatment of ankle sprains. Furthermore, if the ‘Strengthen your ankle’ App indeed does increase intervention uptake this will provide the necessary validation to further develop and enhance this promising role of new media in the implementation of preventive measures and interventions.

Results of this study will become available in 2014.

**Competing interests**

The authors declare no competing interest.

**Authors’ contributions**

EV (e.verhagen@vumc.nl) conceived the research idea. MVR (m.vanreijen@vumc.nl) and EV have written the protocol. MVR will screen and include patients, perform data analysis and be the main author of articles on the primary aim of the study. IV (i.vriend@veiligheid.nl), WVM (w.vanmechelen@vumc.nl) and VZ (v.zuidema@vumc.nl) contributed to ideas in the protocol. All authors have read and commented on the draft version and approved the final version of the manuscript.

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CHAPTER 3
Compliance with Sport Injury Prevention Interventions in Randomised Controlled Trials: A Systematic Review

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Sports Medicine 2016
ABSTRACT

INTRODUCTION: Sport injury prevention studies vary in the way compliance with an intervention is defined, measured and adjusted for.

OBJECTIVE: To assess the extent by which sport injury prevention RCTs have defined, measured and adjusted results for compliance with an injury prevention intervention.

METHODS: An electronic search was performed in MEDLINE, PubMed, the Cochrane Center of Controlled Trials, CINAHL, PEDro and SPORTDiscus. English RCTs, quasi-RCTs and cluster-RCT were considered eligible. Trials that involved physically active individuals, examined the effects of an intervention aimed at the prevention of sport or physical activity related injuries were included.

RESULTS: A total of 110 studies were included. Of all studies, 71.6% mentioned compliance or a related term, 68.8% provided details on compliance measurement, and 51.4% provided compliance data. Only 19.3% analysed the effect of compliance rates on study outcomes. While studies used heterogeneous methods, pooled effects could not be presented.

CONCLUSIONS: Studies that account for compliance demonstrated that compliance significant affects study outcomes. The way compliance is dealt with in preventions studies is subject to a large degree of heterogeneity. Valid and reliable tools to measure and report compliance are needed and should be matched to a uniform definition of compliance.

KEY POINTS:

• Compliance to injury prevention interventions can significantly affect study outcomes

• There is considerable heterogeneity in the way that sports injury prevention studies have measured, defined and reported compliance. More uniformity is needed in future studies to better progress sports injury prevention.
INTRODUCTION

It is widely recognized that participation in regular sports and physical activity has the potential to improve health [1]. However, involvement in such activities also entails a risk of sustaining an injury. Serious sport injuries that take a considerable time to heal can force those involved not only to withdraw from the activity, but also to seek medical care, invest in medication and assisting materials – such as tape, braces, crutches. They can even prevent someone from continuing work or study activities. As a result, injuries lead not only to an individual burden, but also to substantial societal direct and indirect cost [2].

Numerous studies have been performed to evaluate the efficacy of interventions to prevent sport injuries or to reduce the risk of recurrent injury [3]. Although a variety of efficacious preventive interventions have been proposed, implementation of these interventions faces the challenge of persuading participants to follow instructions as prescribed. Establishing the effectiveness of any injury prevention intervention, requires knowledge about what percentage of the targeted population exactly complied with the prescribed protocol. Especially in an intention-to-treat approach, insights into the compliance to the intervention provides valuable, and arguably, necessary information to judge the efficacy of an intervention [4].

When one incorrectly assumes that the entire study population has complied with the intervention protocol, the preventive effect of any intervention can be either over- or underestimated. Unfortunately, many different definitions of compliance have been reported in the sports medicine literature [3]. Both the constructs of compliance and adherence have been used interchangeably to describe the complete and correct following of a prescribed intervention. Nonetheless, the two terms are not synonymous. Compliance refers to participant obedience in a study where a clinician/researcher prescribes the intervention, with little to no right of consultation on behalf of the participant. It can thus be defined as “the athletes’ correct following of the prescribed intervention”. [4] Adherence implicates a more collaborative environment in which a clinician/researcher and a study participant cooperate to develop an intervention that fits with the participants’ opportunities and restraints [5,6]. Research, ideally performed in a more or less controlled setting, therefore implicitly focuses on compliance, rather than on adherence.

In addition to using correct definitions, the operationalization of compliance requires attention. A comprehensive assessment of study results will only be possible if there is thorough insight into the way compliance has been defined, measured and adjusted for. If there is no, or incomplete, information available on the extent to which participants have complied with the intervention, it will remain unclear as to whether the intervention has been truly efficacious or not. Therefore, it is important that researchers, who aim to present studies of high quality with a low risk of bias, acknowledge the importance of compliance, and measure and report upon compliance and its effects on study outcomes.

A number of study reporting guidelines, such as the STROBE statement and the CONSORT statement, recognize the importance of compliance and include specific items on the topic in their guidelines [7-9].

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)
statement addresses cohort, case-control and cross-sectional studies: **CONsolidated Standards Of Reporting Trials (CONSORT)** – specifically addresses the quality of reports of randomized controlled trials (RCTs).

Until 2010, the CONSORT statement advocated the use of intention-to-treat (ITT) analysis for randomized controlled trials. Intention-to-treat analysis does not include the measurement of compliance but assumes full adherence to the prescribed intervention [4]. However, as mentioned in the CONSORT statement, strict ITT analysis ‘is often hard to achieve for two main reasons: missing outcomes for some participants and non-adherence to the protocol. Therefore, since 2010, the CONSORT Statement has replaced the mention of ITT by the requirement of ‘more information on retaining participants in their original assigned groups’ [7]. As an alternative to an ITT analysis, it has been suggested that per-protocol analysis (PPA) – sometimes referred to as ‘modified intention-to-treat’ can be used [4]. In this approach, the analysis is performed only on those participants who have fully complied with the program. A PPA can provide a measurement of efficacy in that it gives the result of a prescribed program that is implemented exactly as the researcher originally has developed it. It is currently unclear to what extent RCTs on sport injury prevention have included the guidelines provided by the CONSORT Statement and to what extent compliance measures have been addressed. This systematic review therefore aims to assess the extent to which sport injury prevention RCTs have defined, measured and adjusted their results for compliance with the trialled intervention/s.

**METHODS**

**Research questions**

This review answers the following questions to provide a detailed analysis on how compliance has been reported in sport injury prevention studies:

1) How and how often was compliance **defined**?

2) When defined, how was compliance **measured**?

3) When defined and measured, how was the outcome **adjusted** for compliance in the analysis?

**Electronic searches**

Seven electronic databases were systematically searched for peer-reviewed publications on sport injury prevention interventions: PubMed (to October 2014), MEDLINE (1966 to October 2014), SPORTDiscus (1949 to October 2014), the Cochrane Central Register of Controlled Trials (to October 2014), CINAHL – Cumulative Index to Nursing and Allied Health Literature (1982 to October 2014), PEDro – The Physiotherapy Evidence Database (to October 2014) and Web of Science (to October 2014). A standardized search strategy,
based on a word string, including relevant sports injury terms and study designs, was used. The following key words, and various combinations of those words, were used in the search: sport injury/ies, athletic injury/ies, prevention, preventive, prevent*, randomiz/s/ed, randomiz/s/ed controlled trial. Reference lists and related citations of included studies and relevant systematic reviews were also hand searched for applicable publications.

**Inclusion criteria**

Only RCTs, quasi-RCTs and cluster-RCT were considered eligible for inclusion. The reason for including only (cluster and/or quasi)RCTs is that these studies maximize internal validity which can be seen as a prerequisite for external validity. Trials were included that involved physically active individuals of either sex and of all ages. To be selected, studies had to examine the effects of an intervention aimed at the prevention of sport or physical activity related injuries. The primary outcome of the studies had to be a measure of sports or physical activity related injury (i.e. injury rate, time to first injury, or the number of injured individuals). Only English language publications were considered.

**Exclusion criteria**

Studies that did not assess prevention of sports injury, that were not a RCT, quasi-RCT or cluster-RCT or did not involve a physically active population were excluded from this review.

**Definitions**

Compliance in this review was defined as "the athletes' correct following of a prescribed intervention" [4]. It is acknowledged that a number of terms have been used in the scientific literature, referring to comparable constructs. As such, for the purpose of this current review, we considered all text referrals to participants’ following of an intervention as compliance. Other examples of phrases equivalent to compliance commonly used in publications are ‘use’, ‘cooperation’ and ‘adoption’ [4]. In this review, all studies included were scrutinized thoroughly to identify the specific form/phrase used by the authors. This ensured that all accounts of compliance were included.

**Methodological quality**

Potentially eligible studies were initially screened by title and abstract by the primary author. When eligibility was unclear, full-text articles were retrieved. In order to assess the methodological quality and risk of bias, all included studies were assessed based on 10 out of 12 criteria as recommended by Furlan et al. [10]. These included the method of randomization, concealed allocation, blinding of participants, blinding of care providers, blinding of outcome assessors, dropout rate, analysis according to allocated group, baseline similarity of the groups, compliance and timing of outcome assessment. This was done to assess if there were differences in the risk of bias between studies that did and did
not report compliance. It is possible that studies that did not report compliance, also failed to report other important methodological and design properties. Two criteria were omitted from Furlan et al. [10]: the reporting without selective outcome and avoidance of co-interventions as these criteria where not considered as distinctive for risk of bias between the included studies.

Each criterion was scored as ‘yes’, ‘unclear’ or ‘no’. Furlan et al. [10] defined studies with more than six points (yes = 1 point) as having ‘low risk of bias’. As two criteria were omitted, the original scoring was adjusted. Hence, more than five points was considered as the cut-off for ‘low risk of bias’.

To familiarize the authors with the risk of bias assessment, three reviewers (MvR, IV and EV) scored ten studies that were randomly selected from all studies. Examining the disagreement in the assessment of these 10 studies allowed the reviewers to identify possible incongruities in scoring. Thereafter, the total number of studies (n=110) was randomly divided in two equal size sets (n=55) and two reviewers (MvR and IV) both independently assessed risk of bias for one set. For the coding reliability assessment, from each of the sets, 19 studies were randomly selected. Both reviewers scored these 38 studies. It was agreed that if the agreement (kappa) score for these 38 studies was >0.9, agreement was acceptable and there was no need for the reviewers to score all studies separately. Out of the 380 items that were scored twice, there was agreement on 370 items. This resulted in an agreement (kappa) score of 0.95. Based on this high level of agreement, it was thus decided that the remainder of the manuscripts did not needed to be assessed by both reviewers.

Data extraction

One reviewer (MvR) scrutinized the included studies for all terms referring to compliance. Thereafter, for the studies that mentioned compliance, details about the definitions, the methods of compliance measurements and the corresponding outcomes were extracted. Finally, all studies were examined for adjustment of the main outcome in their analyses by compliance rates.

RESULTS

Search results

The search strategy initially yielded 1,902 studies, of which, a total of 289 full-text articles were retained after initial screening for eligibility. A total of 180 studies were then excluded (Figure 1), resulting in 109 studies included in this review. Primary reasons for exclusion were that studies did not involve an RCT or did not use injury as an outcome measure. For five studies, full-text articles could not be retrieved [11-15]. Electronic Supplementary Material Appendix S1 provides an overview of the studies included in the final review. Figure 2 describes the included studies in terms of their mentioning of, measurement of and/or adjustment for compliance.
Fig. 1: Literature search flow chart
The 109 included studies scored an average of $4.1 \pm 1.8$ yes ratings (out of 10), $2.8 \pm 1.3$ no ratings and $3.3 \pm 1.8$ unknown (DK’s) on the risk of bias assessment instrument. It can thus be concluded that in general, the included studies demonstrated a fairly high ‘risk of bias’. The 21 studies that explicitly adjusted for compliance rates in their study outcomes – and hence had provided most details on compliance in their report - scored an average of $4.7 \pm 1.6$ on the risk of bias assessment, compared to average scores of $3.9 \pm 1.8$ for the 88 studies that did not account for compliance. This suggests that the studies that accounted for compliance had a slightly higher methodological quality than did those studies without such adjustment. Electronic Supplementary Material Appendix S1, section I provides an overview of the risk of bias score of each of the included studies.
Compliance

Terms used for compliance

Of all studies, 78 (71.6%) mentioned compliance or a related term. Most common was the use of the term ‘compliance’ (n=57, 52.3%). Other terms used were ‘use’ (n=8) and ‘adherence’ (n=6) ‘attendance’ (n=2), ‘cooperation’ (n=1) and ‘participation’ (n=1). Some studies used multiple terms by switching between ‘compliance’ and ‘adherence’ (n=2), ‘compliance’ and ‘exposure’ (n=1) or ‘compliance’ and ‘internal drop-out’ (n=1). Electronic Supplementary Material Appendix S1, section II provides an overview of the terms used in the included studies.

Measurements of compliance

The majority of the 78 studies that mentioned compliance, 75 (68.8% of all studies included) provided details on how they measured compliance. Compliance rates were recorded through a diversity of methods. Studies that concerned supervised exercises derived compliance rates from a written or online report by a supervisor, e.g. a trainer, coach or designated team member (n = 15): [16-30]. Home-based or individual exercises studies made use of a written or online self-report (n=12): [31-42]. In studies relating to the use of protective equipment (orthoses, wrist protectors etc.) or supplements, this use was recorded by either the participant (n=4: [43-46]or a supervisor (n=5): [47-51]. In fifteen studies [47,52-65] the wearing/usage of protective equipment was only checked visually. In three studies [52,54,62], a lack of compliance with wearing/usage of material resulted in prohibition to participate; these studies therefore suggested 100% compliance for people who remained in the study. For example, the participants who were designated to wear a helmet during football were visually checked before they entered the field; non-compliance wearing the helmet resulted in the prohibition to play [52].

In twenty-four studies, researchers verified the reported compliance rates by multiple methods. These included combining self-report with the report of a supervisor [66-70], combining a report of a supervisor with random visits [5,71-78], combining a report of a supervisor with phone calls and visits [79-81], combining self-report with random visits [82], combining a report of a supervisor with phone calls and emails [83] or combining self-report with phone calls [71].

Thirty-one studies included in this review were conducted in a military setting. Although it might be expected that a military setting would make it easier to report on compliance – with many supervised activities and a highly compliant environment – these studies did not provide more details on compliance than other studies. Slightly less than half of the military studies (n= 14) provided details on compliance measurements. In 8 of these 14 studies, it was reported that the participants were visually checked or supervised while carrying out the intervention. Two of those eight studies provided no further details on compliance rates [53,54], two studies excluded participants from the analysis when they did not comply [55,61] and the other four studies reported compliance rates between 57% and 100% [47,56,57,60]. Electronic Supplementary Material Appendix S1, section III provides an overview of ways in which studies have reported compliance rates.
Compliance data and adjustments for compliance rates

Of the 75 studies that provided information on compliance measurement, only 56 studies (51.4% of all included studies) provided compliance data. These data were presented in heterogeneous ways. Nine studies [5,16,67,71,74,79,81,84,85] created subclasses of participants in which high, intermediate and low rates of compliance were defined. However, the (arbitrary) cut-off percentage that was considered for high versus low compliance varied considerably between studies.

For example, in a cluster-RCT on the FIFA 11+ injury prevention program, low, middle and high compliance were defined respectively as performing <24.7%, 24.8-48.1% or >48.2% of all exercises [84]. This resulted in the categorization of 18% teams in the low compliance category, 41% teams with in the moderate compliance category and 41% teams in the high category. In another neuromuscular training intervention cluster-RCT, high compliance was defined as carrying out three (out of 3) sessions in a first intensive intervention period, two sessions in the second intervention period and one session in the third/maintenance period [16]. In this study, 36% of the teams were considered as highly compliant, 43% of the teams as irregularly compliant and 21% of the teams as having interrupted compliance.

Other studies choose to report compliance for each player [5,73,75,79,81,84,86], for the team as a whole [17,19,20,72,74,75,78,79,81,87], or a seasonal compliance rate [20,79]. In addition, some studies combined compliance rates of the intervention and the control group, which were presented as one overall compliance rate [21,22,57,70,82,88,89]. Electronic Supplementary Material Appendix S1, section IV provides an overview of the studies that reported compliance data.

In addition to providing compliance rates, a mere 21 studies [5,16,17,20,31,32,43,58,67,71,74,76,77,79,83-85,88,90,91], (19.3% of all included studies) analysed the effect of different compliance rates on study outcomes. As the studies used heterogeneous methods to report these analyses, it is impossible to provide a pooled effect of compliance rates. Therefore, Table 1 presents the details of the effect of measured compliance rates on their study outcome in these 21 studies.
<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Population</th>
<th>Reported compliance rate (%) in groups being compared</th>
<th>Analysis of the effect of compliance on study outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cobb et al.</td>
<td>Oral contraceptives</td>
<td>Young distance runners</td>
<td>74.5% were seen as compliant. Compliance was defined as using more than 6 months of oral contraceptives.</td>
<td>Compliant women were significantly protected against fractures (by 77%), though this estimate was weakened when we excluded fractures that occurred early in the trial (58% reduction in risk, P = 0.20). The researchers do mention that this finding could have been the result of chance or bias as it was found that women who switched from the control group to oral contraceptive use were less likely to have a history of stress fractures before joining the study.</td>
</tr>
<tr>
<td>Emery et al.</td>
<td>Home-based balance training</td>
<td>PE students</td>
<td>No report of specific compliance rates</td>
<td>Effect of compliance on static but not dynamic balance. Compliance with balance training sessions had an effect on the change in static balance: the observed change among students in the intervention group who reported fewer than 18 sessions over 6 weeks was holding their balance for 6.1 seconds (95% CI –8.4 to 20.7), as compared with 25.8 seconds (95% CI 16.4 to 35.1) among those who reported 18 or more sessions. Compliance did not have a significant effect on change in dynamic balance.</td>
</tr>
<tr>
<td>Engebretsen et al.</td>
<td>Exercise program</td>
<td>Soccer players</td>
<td>Compliance was defined as completing more than 30 sessions: 29.2% for knee exercises, 21.1% for hamstring and 19.4% for groin exercises</td>
<td>No difference was detected in the risk of knee injury between players in the high risk intervention group who were compliant with the knee program (0.2 [95% CI, −0.2 to 0.7] injuries per 1000 hours) and the high risk players in the high risk control group (0.5 [95% CI, 0.2-0.9] injuries per 1000 hours; RR = 0.46; 95% CI,</td>
</tr>
</tbody>
</table>
In the same way, no difference was observed in the incidence of hamstring (RR = 0.94; 95% CI, 0.3-3.2) and groin injuries (RR = 1.6; 95% CI, 0.5-5.6) between players in the high intervention group who were compliant with the respective training programs and the high control group.

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>Participants</th>
<th>Compliance</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabbe et al.</td>
<td>Eccentric hamstring exercises</td>
<td>Amateur Australian Football players (114/106, 100%)</td>
<td>46.8% participated in more than 2 sessions</td>
<td>Significant difference due to compliance. When only control and intervention group players who participated in at least the first two sessions were analyzed, a trend towards a protective effect for the intervention group was noticed (RR 0.3, 95% CI: 0.1, 1.4; p = 0.098). Only 4% of the compliant group sustained an injury compared to 13.2% in the control group (no p-value specified).</td>
</tr>
<tr>
<td>Hagglund et al. [74] 2013</td>
<td>Neuromuscular training program</td>
<td>Soccer players (2471/2085, 0%)</td>
<td>79% team compliance. Team compliance was defined as completing a supervised neuromuscular training.</td>
<td>Teams with the highest level of compliance (89%) had 88% lower risk of re-injury rate compared to control and low compliance (63%) teams. Low and control were not significantly different.</td>
</tr>
<tr>
<td>Hupperets et al. [32] 2009</td>
<td>Proprioceptive training</td>
<td>Athletes with an ankle sprain (256/266, 52.4%)</td>
<td>Fully compliant: 23%, partially compliant 29%, non-compliant 35%, unknown 13%. A definition of compliance was not provided.</td>
<td>Although a significant reduction in risk of injury was found in all groups, the researchers suggest that a higher compliance might have resulted in fewer recurrent injuries.</td>
</tr>
<tr>
<td>Kiani et al. [20] 2010</td>
<td>Exercise program + education</td>
<td>Soccer players (777/729, 0%)</td>
<td>6% of players were 50% compliant, 75% were 75% compliant and 18% were 100% compliant. A definition of compliance was not provided.</td>
<td>Including only compliant teams; there was a non-significant different rate ratio in the intervention group compared with controls for all injuries (0.17 (95% CI, 0.02-0.75)) and for noncontact injury 0.11 (0.95% CI, 0.02-0.77).</td>
</tr>
<tr>
<td>Study</td>
<td>Group Description</td>
<td>Participants</td>
<td>Compliance</td>
<td></td>
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<tr>
<td>Larsen et al. [68] 2002</td>
<td>Custom made shoe orthoses</td>
<td>Conscripts (77/69, 99.3%)</td>
<td>88.3% overall (control and intervention). A definition of compliance was not provided.</td>
<td></td>
</tr>
<tr>
<td>Longo et al. [83] 2012</td>
<td>FIFA 11+ warm-up</td>
<td>Basketball players (80/41, 100%)</td>
<td>100% compliance. A definition of compliance was not provided.</td>
<td></td>
</tr>
<tr>
<td>Machold et al. [58] 2002</td>
<td>Wrist protectors</td>
<td>Students (342/379, 60%)</td>
<td>96.5% A definition of compliance was not provided.</td>
<td></td>
</tr>
<tr>
<td>McIntosh et al. [76] 2009</td>
<td>Padded headgear</td>
<td>Rugby players (1493/1128/1474/100%)</td>
<td>Standard: 48.9%, modified: 40.1%. Compliance was defined as wearing headgear.</td>
<td></td>
</tr>
<tr>
<td>Myklebust et al. [17] 2007</td>
<td>Neuromuscular training</td>
<td>Handball players (850/942, 0%)</td>
<td>1st season 26% &amp; 42% elite, 2nd season 29% &amp; 50% elite, youth 87%. Compliance was defined as conducting a minimum of 15 ACL injury prevention sessions during the 5-7 week period with more than 75% of the athletes participating.</td>
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</tbody>
</table>

ITT analysis gave an RR of 0.7 (0.5-1.1) and PPA analysis an RR of 0.3 (0.1-0.7).

In the intervention group, IID's were lower than those in the control group for overall injuries (0.95 vs 2.16; $P = .0004$), training injuries (0.14 vs 0.76; $P = .007$), lower extremity injuries (0.68 vs 1.4; $P = .022$), acute injuries (0.61 vs 1.91; $P = .001$), and severe injuries (0 vs 0.51; $P = .004$). The intervention group also had lower injury rates for trunk (0.07 vs 0.51; $P = .013$), leg (0 vs 0.38; $P = .007$), and hip and groin (0 vs 0.25; $P = .023$) compared with the control group. Differences in match injuries, knee injuries, ankle injuries, and overuse injuries between 2 groups were not significant.

The risk of severe wrist injury decreased by a factor 0.13 using the protector.

Head injury and concussion rates based on headgear-wearing compliance were not significantly different.

There was downward trend in the number of injuries during the study period, as compliance seemed to improve. Due to a crossover effect of 22%, both teams, showed a significant lower rate of injuries.

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1 In this study participants were assigned to three different study groups: the control group, the standard headgear group and the modified headgear group.
<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Sport/Activity</th>
<th>Compliance/Injury Details</th>
<th>Outcome/Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasanen et al. [16] 2008</td>
<td>Neuromuscular training</td>
<td>Floor ball players (256/201, 0%)</td>
<td>74% High compliance was defined as carrying out at least three trainings a week during the first intensive period, at least twice a week during the second intensive period, and at least once a week during the maintenance weeks.</td>
<td>Intervention teams with high compliance to the neuromuscular training had a lower risk of injury than the control group: the incidence rate ratio between the high compliance group and control group for non-contact leg injury was 0.19 (95% confidence interval 0.06 to 0.64, ( P=0.007 )), for non-contact ankle ligament injury 0.19 (0.05 to 0.82, ( P=0.026 )), and for non-contact knee ligament injury 0.32 (0.04 to 2.59, ( P=0.284 )).</td>
</tr>
<tr>
<td>Ronning et al. [91] 2001</td>
<td>Wrist protectors</td>
<td>Snowboarders (2515/2514, 64.2%)</td>
<td>99.5% A definition of compliance was not provided.</td>
<td>In the braced group, 8 wrist injuries (3 fractures and 5 sprains) were recorded, compared with 29 wrist injuries (2 fractures and 27 sprains) recorded in the control group. Considering all types of injuries, a total of 33 injuries occurred in the braced group and 51 in the control group. This is a significant difference in favor of the braced group (chi-squared test: ( \chi^2 = 3.9, P=0.05 )).</td>
</tr>
<tr>
<td>Soderman et al. [67] 2000</td>
<td>Balance board training</td>
<td>Soccer players (62/78, 0%)</td>
<td>70%. Compliance is defined as performing more than 70 sessions.</td>
<td>In the intervention group, no significant difference was found in the number of traumatic injuries or injured players between those who were compliant (n=27) and those who were non-compliant (n=35) sub groups.</td>
</tr>
<tr>
<td>Soligard et al. [79] 2008</td>
<td>FIFA 11+ warm-up</td>
<td>Football players (1055/1220, 0%)</td>
<td>77% (team) and 57.9% (player), high compliance (33-95 sessions), intermediate compliance (15-32 sessions), low compliance (0-14 sessions)</td>
<td>The risk of injury was 35% lower in intervention players in the third with the highest compliance 2.6 (2.0 to 3.2) injuries/1000 player hours, compared with players in the intermediate third 4.0 (3.0 to 5.0) injuries/1000 player hours (rate ratio 0.65, 0.44 to 0.94, ( P=0.02 )). The 32% reduction in risk of injury compared with the third with the lowest compliance (3.7 (2.2 to 5.3) injuries/1000 player hours did not</td>
</tr>
<tr>
<td>Study</td>
<td>Study Year</td>
<td>Intervention</td>
<td>Population</td>
<td>Compliance</td>
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</tr>
<tr>
<td>Soligard et al. [81]</td>
<td>2010</td>
<td>FIFA 11+ warm-up</td>
<td>Football players (1055/1220, 0%)</td>
<td>77% (team) and 57.9% (player), high compliance (33-95 sessions), intermediate compliance (15-32 sessions), low compliance (0-14 sessions)</td>
</tr>
<tr>
<td>Steffen et al. [80]</td>
<td>2008</td>
<td>FIFA 11+ warm-up</td>
<td>Football players (1091/1001, 0%)</td>
<td>52%, compliant &gt;20 sessions, non-compliance &gt; 20 sessions</td>
</tr>
<tr>
<td>Steffen et al. [84]</td>
<td>2013</td>
<td>FIFA 11+ warm-up</td>
<td>Football players</td>
<td>Intervention 1: High, medium, low compliance: 52%, 23%, 25%. Intervention 2: High, medium, low compliance: 41%, 41%, 18%. Team compliance was defined as</td>
</tr>
<tr>
<td>Steffen et al. [85] 2013</td>
<td>FIFA 11+ warm-up</td>
<td>Football players (68/78/80, 0%)(^2)</td>
<td>Intervention 1: High, medium, low compliance: 37%, 23%, 8%. Intervention 2: High, medium, low compliance: 29%, 26%, 23%. Team compliance was defined as the 11+ the proportion of all possible sessions where the 11+ was delivered, the number of team 11+ sessions/week and the mean number of team 11+ exercises/session.</td>
<td>However, adjusting for the cluster, age group, level of play and injury history, this between-group difference in injury risk was not statistically significant (IRR=0.44, 95% CI 0.18 to 1.06). No other dose-response relationship between high and low adherence to the 11+ and injury risk could be identified.</td>
</tr>
<tr>
<td>Walden et al. [77] 2012</td>
<td>Neuromuscular training</td>
<td>Football players (2479/2080, 0%)</td>
<td>Compliance defined as &gt;1 session per week: 52.5%</td>
<td>An adjusted subgroup analysis of compliant players (1303 players in 112 intervention group clubs, 1967 players in 106 control group clubs) showed a statistically significant 83% rate reduction in anterior cruciate ligament injury (rate ratio 0.17, 0.05 to 0.57, (P=0.004)), as well as significant reductions for secondary outcomes in the intervention group compared with the control group (severe knee injury rate ratio 0.18, 0.07 to 0.45, (P&lt;0.001); any acute knee injury rate ratio 0.53, 0.30 to 0.94, (P=0.03)). Analyses of non-contact anterior cruciate ligament injuries showed a reduction in rates favouring the intervention group. The reduction was statistically significant only for the</td>
</tr>
</tbody>
</table>

\(^2\)In this study participants were assigned to three different study groups: an unsupervised group, a group who received coach-led workshops and a group who received coach-led workshops and on-field supervision.
Table 1: Studies that analyze the effect of compliance rates on study outcome

<table>
<thead>
<tr>
<th>PE</th>
<th>RR</th>
<th>ITT</th>
<th>PPA</th>
<th>IRR</th>
<th>IID</th>
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</tbody>
</table>

adjusted subgroup analysis of compliers (intention-to-treat analysis rate ratio 0.40, 0.13 to 1.18, P=0.10; adjusted subgroup analysis rate ratio 0.26, 0.07 to 0.99, P=0.049).

PE = Physical education, RR = Relative Risk, ITT = Intention-to-treat, PPA = Per-protocol-analysis-treat, IRR = Incidence rate ratio, IID = Injury incidence density.
DISCUSSION

A lack of a uniform definition of compliance

In the studies presented in this review, various methods were employed to define measure and analyse the effect of compliance. The most important finding is that, although the majority of studies mention the concept of compliance, there is a large degree of heterogeneity in the manner in which studies deal with this concept. Some studies merely mention compliance in either the introduction or discussion without providing further details on compliance assessment and compliance data. As can be seen from Figure 2 there are more studies that provide compliance data than there are studies that give an explicit definition of compliance or one of the related constructs. In other words, whilst many report compliance, a majority do not define this term or explicitly state how they operationalized it.

The majority of the studies report minimal details on: (1) the definition of compliance, 2) how compliance was measured, 3) the frequency by which compliance was measured (every day, week, month), and 4) how compliance affected study outcomes. From 1970 onwards, there was a clear increase in the number of sport injury prevention RCT studies. However, in the last few years (2011-2014) this trend has not continued and the number of injury prevention RCTs has actually decreased. It is likely that after numerous efficacy studies, research now focuses on implementation of prevention measures in non-RCT studies. As these non-RCT studies are not the topic of this review, they will not appear in Figure 2.

The importance of compliance reporting

In order to evaluate study outcomes in the context in which they are examined, it is essential that studies report the percentage of participants who have actually complied with the prescribed intervention. Compliance to an intervention significantly influences the outcomes of intervention studies, which is clearly illustrated by a number of studies included in this review [5,32,71,74,90]. For example, in the study by Steffen et al. [5] that assessed compliance rates to a neuromuscular injury prevention programme, high, intermediate and low compliance groups were defined. The author’s PPA found that only the high compliant group benefited significantly from the intervention.

In the study by Emery [71] evaluating home-based balance training, participants who had conducted more than 18 sessions (out of the recommended 42 sessions) in 6 weeks had achieved a significant improvement in static balance skills. Participants with lower compliance rates did not improve their static balance skills. Gabbe et al. [90] evaluated eccentric hamstring exercises in amateur football players, of which only 4% of those who were compliant with the intervention sustained an injury. Players who were not compliant to the intervention showed no reduced injury risk when compared to the control group. Hagglund et al. [74] reported similar outcomes, showing that only in teams with highest compliance to a neuromuscular training program a significant reduction in injury rates was found. Finally, the study of Hupperets et al. [32] suggested that a higher compliance would have resulted in fewer injuries. In that study, only 23% of participants were fully compliant. In a secondary analysis in a subsequent paper, it was indeed shown that the small group of...
participants with high compliance was responsible for the positive effect of the exercise program on recurrent injury risk [92].

Information on the rate of compliance and its effect on study outcomes can be shaped into a clear message for the target groups involved; they should be informed about the number of training sessions they should at least participate in to reduce their risk of sustaining an injury. Providing information on compliance rates and the effect of those different rates on study outcomes might increase the practical usability of study results for the target group.

**Acknowledgment of the CONSORT Statement**

The CONSORT statement argues that, in order to evaluate both efficacy (with the assumption of full compliance and no recognition of implementation barriers) and effectiveness (the real life adoption of an intervention), researchers should analyse study results using ITT, PPA and a graded compliance measure [7]. The latter refers to the extent to which participants have complied with the program and what effect this has had on the outcome.

In addition to the diversity by which compliance is defined, measured and adjusted for in the analysis, the studies included in this review show a large degree of heterogeneity in the use of ITT, PPA or graded compliance.

Thirty-seven studies have used one or more of the recommended analyses. Twenty-eight studies [16,17,27,29,32,34,37-40,42,44,50,52,71,72,75-82,84,93-95] used ITT analysis, one used PPA [19] and eight studies [31,43,47,58,88,90,96,97] used both analyses (see Electronic Supplementary Material Appendix S1). It is clear that, although the CONSORT statement clearly acknowledges the importance of compliance and hence, provides a step forward in improving the quality of intervention studies, there is still a lack of uniformity. What is needed is a uniform way in which compliance is dealt with.

**Further research**

Further research needs to confirm which measures provide the most valid and reliable assessment of compliance. Although various methods have been used to measure compliance (e.g. the use of written, vocal or online self-reports, supervision and/or unscheduled visits), each method has its own limitations. Participants can incorrectly recall their activities or provide socially desirable reports on self-reported measures of compliance. In addition, a uniform definition of compliance and a categorization of compliance rates might increase the possibility of comparing the effectiveness of different injury prevention programs. The main weakness of the current study is that it only included RCTs. It would be of interest to conduct a similar review that includes both RCTs and less-controlled studies to identify adherence to sport injury intervention studies in which the setting is less controlled.
CONCLUSION

Injury prevention studies vary significantly in the way they define, measure and adjust for compliance. While the majority of these studies mention the concept of compliance, only one fifth of the studies gave a more detailed account of how compliance rates influence their study results. The studies that did account for compliance, demonstrate that the level of compliance can have a significant effect on study outcomes. Valid and reliable tools to measure and report compliance need to be developed, matched to a uniform definition of compliance. Although current guidelines for reporting of studies have increased awareness of the need for compliance measurements, the way these measurements are executed and reported still deals with a large degree of heterogeneity.

COMPLIANCE WITH ETHICAL STANDARDS

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Conflicts of Interest
Miriam van Reijen, Ingrid Vriend, Willem van Mechelen, Caroline Finch and Evert Verhagen declare that they have no conflicts of interest relevant to the content of this review.
REFERENCES


REFERENCES


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CHAPTER 4

Increasing compliance with neuromuscular training to prevent ankle sprain in sport: does the ‘Strengthen your ankle’ mobile App make a difference? A randomised controlled trial.

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Ingrid Vriend
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ABSTRACT

Background E-health has the potential to facilitate implementation of effective measures to prevent sports injuries.

Aim: We evaluated whether an interactive mobile application containing a proven effective exercise programme to prevent recurrent ankle sprains, resulted in higher compliance as compared to regular written exercise materials.

Methods 220 athletes participated in this randomised controlled trial with a follow-up of eight-weeks; 110 athletes received a booklet explaining an eight-week neuromuscular training program; 110 athletes the same program in an interactive mobile App (‘Strengthen your ankle’). The primary outcome was compliance with the exercise program. Secondary outcome measure was the incidence density of self-reported recurrent ankle sprains.

Results The mean compliance to the exercise scheme was 73.3% (95% CI: 67.7-78.1) in the App group, compared to 76.7% (95% CI: 71.9-82.3) in the Booklet group. No significant difference in compliance was found between groups. The incidence densities of self-reported time-loss recurrences were not significantly different between both groups (HR 3.07; 95% CI 0.62-15.20).

Summary: This study shows that the method of implementing the exercises by using an App or a Booklet does not lead to different compliance rates.

New findings: The use of a mobile App or a Booklet lead to similar compliance and injury rates in the short term.

Trial registration

The Netherlands National Trial Register NTR 4027. The NTR is part of the WHO Primary Registries.
BACKGROUND

Ankle injuries are the second most common sports related injuries and ankle sprain is the most common type of ankle injury. Ankle sprain may account for as much as 80% of all ankle injuries. The incidence of ankle injury and ankle sprain is especially high in popular sports as rugby, (indoor) soccer, triathlon, handball, volleyball and basketball [1]. Both externally applied supports (i.e. taping or bracing of the ankle), as well as neuromuscular training programs prevent recurrent ankle sprains and are cost-effectiveness [2,3,5].

Despite these cost-effective interventions, large-scale community uptake of these measures, and thus actual prevention of ankle sprains, is lagging [4,5]. The cost-effective neuromuscular training program [3,6] has suffered from poor compliance [4] and its preventive effect was achieved solely among a subsample of compliant athletes [5]. Although analyses have been performed using an intention-to-treat approach, there is still a lot of effectiveness to gain by increasing compliance with preventive measures.

E-health has potential to bridge this so-called implementation gap [7]. The company VeiligheidNL developed an interactive mobile application: 'Strengthen your ankle' ('Versterk je enkel', free for iOS and Android) that contains the cost-effective neuromuscular training program. Although mobile apps are plentiful and have the cachet of technological advancement, the value of this approach for injury prevention has not been evaluated formally [8]. Consequently, we evaluated whether the ‘Strengthen your ankle’ App resulted in higher compliance with the neuromuscular training program as compared to the regular written exercise materials.

METHODS

Design

This study was a randomised controlled trial. A detailed description of the study protocol has been published elsewhere [9]. The study design, procedures and informed consent procedure were approved by the Medical Ethics Committee (2013/248) of the VU University Medical Center Amsterdam (VUMc) the Netherlands. The trial is registered in the Netherlands Trial Registry (NTR4027).

Participants

Participants were recruited from October 2013 to April 2014 through physiotherapy and sport physician practices, national sport federations’ websites, digital newsletters and an open invitation via social media, the Internet and written media. Active sports participants (athletes) between 18 and 70 years of age who had sustained an ankle sprain within the past two months, and who had access to a mobile phone (either Android or iOS), were eligible for inclusion. Respondents were excluded if they had sustained an injury other than a lateral ankle sprain in the same ankle in the preceding year (e.g., fracture of the ankle). Before inclusion, the main author contacted all potential participants by phone to confirm study eligibility. The recruitment of participants is shown in Figure 1.
Sample Size

Sample size calculations were based upon the primary outcome measure compliance and originated from previously established compliance rates to the same program when advocated through written materials [4]. Full compliance rates in the written materials' group were expected to be around 25%. A doubling of this rate to at least 50% was considered to be clinically relevant. Based upon a beta of 0.90 and an alpha of 0.05, a total of 158 athletes were required divided across both study groups. Assuming a dropout rate of 20%, a sample of 190 participants was calculated.

Randomisation procedure

After participants had finished ankle sprain treatment by means of usual care, and after the baseline questionnaire and the informed consent were received, participants were randomly assigned to one of two study groups. The control group received the neuromuscular training program on paper (Booklet group) and the intervention group
received the neuromuscular training program through the App (App group). Participants were allocated to the study groups through a random number generator.

**Interventions**

All participants received the neuromuscular training balance board (machU/ MSG Europe BVBA). Both the Booklet and the App contained the same neuromuscular training program. The App can be downloaded for free from both the App Store (http://apple.co/1EcHyFP) and the Google Play store (http://bit.ly/1AHuZkB). Whereas the App provided the user with instructional videos and verbal instructions, the Booklet included only pictures of the exercises that needed to be performed. The embedded neuromuscular training program consisted of six different exercises to be performed during three sessions a week, with a maximum duration of 30 minutes per session, for a period of 8 weeks. Exercises gradually increased in difficulty and load during the course of eight weeks. This program has been shown to be cost-effective in reducing recurrent ankle sprain [6]. A full description of the program has been published elsewhere [4]. Figure 2 shows the exercises, and Table 1 gives the scheme that participants were required to follow.

**Figure 2** The exercises of the neuromuscular training program
Table 1 | Exercise scheme of the 8-week neuromuscular training program

<table>
<thead>
<tr>
<th>Exercise</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>Week 8</th>
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<tr>
<td>B</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>C</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
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<td>2</td>
<td>3</td>
<td>3</td>
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<tr>
<td>D</td>
<td>1</td>
<td>1</td>
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<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
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<td>E</td>
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<td>1</td>
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<td>2</td>
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<td>3</td>
<td>3</td>
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<tr>
<td>F</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Baseline measurement

An online baseline questionnaire collected information from each participant on demographic variables, physical characteristics, sports and injury history, use of preventive measures, severity and received treatment and/or rehabilitation of the current ankle sprain.

Outcome measures

The primary outcome measure was compliance to the exercise scheme prescribed in the neuromuscular training program. Compliance was defined as the participant’s following of the prescribed intervention, i.e. the scheme of exercises (Table 1) [10]. Compliance measurements commenced after the start of the allocated intervention and took place weekly for the duration of the program (eight weeks). Participants received a request by email to complete an online compliance questionnaire. After three days a reminder was sent in case of non-response. These weekly measurements gathered information for each participant on the number of executed exercises per session and the number of executed sessions per week. From this information, weekly compliance rates were calculated as the percentage of prescribed exercises conducted, by multiplying the percentage per exercise with the number of times these exercises were performed per week. Previous research has shown that, in order for the neuromuscular program to be effective, participants have to be highly compliant with the exercise scheme [10]. In this study, a compliance rate of over 75% was considered adequate.
Exposure and injury registration

Secondary outcome measure was the incidence density of self-reported recurrent ankle sprains. Injury incidence density was defined as the number of recurrent ankle sprains per 1,000 hours of sports exposure. During the eight weeks follow-up, in addition to the questions regarding compliance, participants were asked weekly about their hours of sports exposure and whether they had sustained an ankle sprain in the previous week. Ankle sprain recurrence was defined as a self-reported inversion moment of the same ankle. Both an episode of giving-was, as well as a grade 1, 2 or 3 ankle sprains were registered. Self-reported recurrent ankle sprains were further categorized to severity by looking at recurrences that had led to time-loss, defined as the discontinuity of (sport) activity and / or missing (part of) the next planned (sports) activity due to the recurrence [4]. This time-loss categorization is in line with the accepted definition of an ankle sprain [11].

Statistical analyses

Mean baseline differences between the App and the Booklet group were determined using an independent samples t-test for continuous data (age, weight, height, exposure) and Fisher’s exact test (with Monte Carlo 95% confidence interval simulation due to small number of samples) for categorical data (level of sport, severity of ankle sprain, gender). Baseline measurements were based on the total number of participants (n=220) that were allocated to either one of the interventions.

While compliance was not normally distributed, weekly and overall compliance means and corresponding 95% CI were obtained through bias corrected accelerated bootstrapping with 1,000 bootstrap samples. Mean weekly and overall compliance rates were compared between groups by means of a non-parametric Mann-Whitney U test. Cox regression analyses compared risk of self-reported and time loss recurrent ankle sprains between the groups. Analyses were checked for confounding by baseline variables, but none were found. Gender was found to be an effect modifier; consequently, analyses were done separately for both males and females. All analyses were conducted according to the intention-to-treat principle and differences were considered significant with a significance level of .05.

RESULTS

Recruitment

Between October 2013 and April 2014, a total of 220 participants were recruited and randomized to one of the two groups (Figure 1). After randomization, a number of participants indicated that they no longer wished to participate in the study due to time restraints or lack of motivation. For the remainder of the study period, their compliance rates were set to 0%. A small number of participants had to leave the study due to a non-ankle injury (n=4) or due to personal reasons (n=4). The compliance rates of these
participants were only included for the weeks they participated in the study. At baseline, both groups were comparable regarding all variables measured (Table 2).

Table 2 Baseline characteristics of the study population. Numbers are presented as percentage of the population (%) or as the mean with corresponding standard deviation (mean ± SD).

<table>
<thead>
<tr>
<th></th>
<th>Combined</th>
<th>App</th>
<th>Booklet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants (n)</td>
<td>220</td>
<td>110</td>
<td>110</td>
</tr>
<tr>
<td>Number of females (%)</td>
<td>50.0%</td>
<td>50.0%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>37.9 ± 13.4</td>
<td>37.6 ± 13.1</td>
<td>38.1 ± 13.7</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>73.3 ± 12.8</td>
<td>73.0 ± 13.0</td>
<td>73.7 ± 12.6</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>177.3± 9.1</td>
<td>177.0 ± 8.9</td>
<td>177.7 ± 9.4</td>
</tr>
<tr>
<td>Level of sport (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competitive. international</td>
<td>8.2</td>
<td>1.8</td>
<td>6.4</td>
</tr>
<tr>
<td>Competitive. national</td>
<td>29.1</td>
<td>17.3</td>
<td>11.8</td>
</tr>
<tr>
<td>Competitive. regional</td>
<td>69.1</td>
<td>36.4</td>
<td>32.7</td>
</tr>
<tr>
<td>Recreational. organised</td>
<td>50.9</td>
<td>22.7</td>
<td>28.2</td>
</tr>
<tr>
<td>Recreational. unorganised</td>
<td>42.7</td>
<td>21.8</td>
<td>20.9</td>
</tr>
<tr>
<td>Severity of inclusion sprain (%)</td>
<td>84.6</td>
<td>42.7</td>
<td>41.8</td>
</tr>
<tr>
<td>Grade 1</td>
<td>58.2</td>
<td>30.9</td>
<td>27.3</td>
</tr>
<tr>
<td>Grade 2</td>
<td>16.4</td>
<td>9.1</td>
<td>7.3</td>
</tr>
<tr>
<td>Unknown</td>
<td>40.9</td>
<td>17.3</td>
<td>23.6</td>
</tr>
</tbody>
</table>

**Compliance**

Over the complete 8 weeks, the mean compliance to the exercise scheme was 73.3% (95% CI: 67.7-78.1) in the App group as compared to 76.7% (95% CI: 71.9-82.3) in the Booklet group (Table 3). No significant difference in mean overall compliance was found between groups, nor for males or females. In both groups 82 out of 110 participants (74.5%) complied to more than 75% of the program. Compliance gradually declined over the 8 weeks in both groups (Figure 3).
<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>App</td>
<td>Booklet</td>
<td>App</td>
</tr>
<tr>
<td>Week 1</td>
<td>90.2%</td>
<td>91.3%</td>
<td>91.5%</td>
</tr>
<tr>
<td></td>
<td>(84.4-94.9)</td>
<td>(86.8-95.3)</td>
<td>(84.0-98.2)</td>
</tr>
<tr>
<td>Week 2</td>
<td>78.3%</td>
<td>82.3%</td>
<td>80.6%</td>
</tr>
<tr>
<td></td>
<td>(70.9-84.8)</td>
<td>(75.2-88.4)</td>
<td>(71.4-90.3)</td>
</tr>
<tr>
<td>Week 3</td>
<td>76.8%</td>
<td>78.9%</td>
<td>76.7%</td>
</tr>
<tr>
<td></td>
<td>(69.7-83.5)</td>
<td>(72.0-84.6)</td>
<td>(67.1-85.5)</td>
</tr>
<tr>
<td>Week 4</td>
<td>72.7%</td>
<td>75.5%</td>
<td>70.6%</td>
</tr>
<tr>
<td></td>
<td>(65.2-79.7)</td>
<td>(67.8-82.6)</td>
<td>(61.0-80.3)</td>
</tr>
<tr>
<td>Week 5</td>
<td>67.1%</td>
<td>75.3%</td>
<td>68.5%</td>
</tr>
<tr>
<td></td>
<td>(58.9-74.2)</td>
<td>(67.2-82.8)</td>
<td>(57.9-78.6)</td>
</tr>
<tr>
<td>Week 6</td>
<td>70.2%</td>
<td>67.9%</td>
<td>70.7%</td>
</tr>
<tr>
<td></td>
<td>(61.7-77.8)</td>
<td>(60.4-75.7)</td>
<td>(60.1-81.3)</td>
</tr>
<tr>
<td>Week 7</td>
<td>63.3%</td>
<td>70.5%</td>
<td>58.2%</td>
</tr>
<tr>
<td></td>
<td>(54.2-71.9)</td>
<td>(62.8-77.9)</td>
<td>(45.7-70.3)</td>
</tr>
<tr>
<td>Week 8</td>
<td>64.1%</td>
<td>66.2%</td>
<td>61.6%</td>
</tr>
<tr>
<td></td>
<td>(55.7-72.5)</td>
<td>(57.7-74.6)</td>
<td>(50.3-73.9)</td>
</tr>
<tr>
<td>Overall</td>
<td>73.3%</td>
<td>76.7%</td>
<td>71.8%</td>
</tr>
<tr>
<td></td>
<td>(68.0-78.5)</td>
<td>(71.7-81.9)</td>
<td>(63.9-78.6)</td>
</tr>
</tbody>
</table>
**Figure 3** | Mean weekly compliance rates and corresponding 95% CI of both groups across the 8 weeks of the neuromuscular training program.

**Exposure and recurrent injury**

In total, participants took part in 2,429 hours of sport in the App group and 2,547 hours of sport in the Booklet group during the eight-week program. In the eight weeks of the exercise program 93 self-reported recurrent ankle sprains were reported, resulting in injury incidence densities of respectively 25.3 self-reported recurrences per 1,000 hours (95% CI: 18.0-32.7) in the App group, and 25.6 self-reported recurrences per 1,000 hours (95% CI: 18.3-32.9) in the Booklet group (Table 4). The injury incidence densities of time-loss ankle sprains were respectively 0.82 time-loss recurrences per 1,000 hours (95% CI: -0.3-2.0) in the App group, and 2.36 time-loss recurrences per 1,000 hours (95% CI: 0.5-4.2) in the Booklet group. No significant differences in injury incidence densities between groups were found for either self-reported or time loss recurrent injuries.

Gender acted as an effect modifier in the relationship between group allocation and injury recurrence outcome. No significant differences were found between genders.
Table 4 Injury incidence density (IID) of self-reported and time loss ankle sprain recurrences (95% CI) per 1,000h of sports participation, as well as the Hazard Ratio (95% CI) derived from Cox regression analyses.

<table>
<thead>
<tr>
<th>Recurrent ankle sprain</th>
<th>App</th>
<th>Booklet</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>n</td>
<td>IID</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
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<tr>
<td>Self-reported</td>
<td>46</td>
<td>25.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(18.0 - 32.7)</td>
</tr>
<tr>
<td>Time loss</td>
<td>2</td>
<td>0.82</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(-0.3 - 2.0)</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported</td>
<td>21</td>
<td>17.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(9.7 – 24.2)</td>
</tr>
<tr>
<td>Time loss</td>
<td>1</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(-0.7 – 2.0)</td>
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<tr>
<td>Female</td>
<td></td>
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<tr>
<td>Self-reported</td>
<td>25</td>
<td>43.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(26.3 – 60.3)</td>
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<tr>
<td>Time loss</td>
<td>1</td>
<td>1.0</td>
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<td></td>
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<td>(-1.0 – 3.1)</td>
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</table>

DISCUSSION

We found that the method of implementing the ‘Strengthen your Ankle’ exercise scheme, by using an App or a Booklet, did not lead to significant different mean overall compliance rates. Also, the percentage of participants that were highly compliant was not different between groups. In both groups 74.5% of participants complied with the neuromuscular training program.

Comparison with previous studies

The current study is the first to compare compliance rates to a preventive intervention program under the influence of different implementation methods. Two previous studies have tested the effectiveness of the same neuromuscular training program using written
materials, and both studies reported compliance rates [4,5]. The percentage of participants who were fully compliant during the two months of the program was as low as 23%\(^4\). Janssen et al. [5] described full compliance of 45%. In the current study, the percentage of participants that were highly compliant was 65%, Janssen et al. [15] argued that at the time of their study the neuromuscular training program was more widely accepted in the Netherlands than some years before, explaining the higher compliance rates in their study. It is possible that the neuromuscular training program at the time of our study has increased acceptance in practice even further. In addition, the previous studies used a printed-paper with a simple lay-out. Both the Booklet and the App used in the current study were updates of the materials that have been used in the previous studies. We speculate that the Booklet and the App employed in our study may have had a more attractive format that resulted in increased compliance rates.

**Effect on injuries**

Injury incidence densities of self-reported recurrences between the App group and the Booklet group were not significantly different. In two previous studies that evaluated the same neuromuscular training program, reductions in injury risk were observed under the influence of the program [4,5]. Janssen et al. [5] reported an overall injury incidence density of 2.51 recurrent ankle sprains per 1,000h of sport (95% CI: 1.51-3.42) in the group that followed the program. Hupperets et al. [4] found an ankle sprain injury incidence density of 1.86 per 1,000h of sport (95% CI: 1.28-2.75). These injury incidence densities are considerably lower than found in our study. A main difference between the previous studies and the current study is that an inversion moment (giving-way) was also counted as a recurrent event in the current study. Hence this may explain the disparity in injury incidence densities between our study and previously reported injury incidence densities. Comparing only the injury incidence densities of recurrent injuries that led to time-loss, the results of Hupperets et al. [4] (0.65 per 1,000h of sport; 95% CI: 0.38-0.92), and Janssen et al. [5] (0.95 per 1,000h of sport; 95% CI: 0.39-1.51) are more comparable to our findings.

We note a trend for App users to have reported a lower rate of recurrent ankle sprain with time loss. However, due to the low number of recurrent injuries that were reported and the relative short time span of follow-up, we lacked statistical power to comment on this result. One could speculate that the App may promote better quality execution of the exercises. Where the Booklet contained printed instructions and images on how to properly execute the exercises, the App contained videos and verbal instructions on the correct execution of the exercises. This may have helped participants to correctly execute the exercises. In a recent study among athletes who were ‘compliant’ with an exercise scheme, only 67% performed the exercises as described [12]. Incorrect execution of exercises may diminish the preventive effect of an exercise. Our data provide the basis to study this question with appropriate power.
**Methodological considerations**

One could argue that in practice patients, who are not involved in a study, might have lower compliance rates that those we report here. Participants who volunteered to participate in the study may already be inherently more motivated to perform the exercises. Additionally, the weekly questionnaires used in the study allowed for a weekly reminder and the compliance with the exercises was assessed through self-report. The obligation to report missed exercises may have increased self-reported compliance rates. This should be taken into account when interpreting the reported compliance rates.
Summary

The current study showed that the method of implementing the exercises through an App or a Booklet does not lead to different compliance rates. Both methods resulted in around 75% of the participants performing an adequate number of exercises.

Competing interests

The authors declare no competing interest. VeiligheidNL has provided the mobile App. However, this App is available for free.

Contributors

EV (e.verhagen@vumc.nl) conceived the research idea, MVR (m.vanreijen@vumc.nl, @miriamvanreijen) and EV have written the protocol, MVR has screened and included patients, performed data analyses and is the main author. IV (i.vriend@veiligheid.nl), WVM (w.vanmechelen@vumc.nl) and VZ (v.zuidema@veiligheid.nl) contributed to ideas in the protocol. All authors have read and commented on the draft version and approved the final version of the manuscript.

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Patient consent

Obtained

Ethics approval

The study was approved by the medical ethics committee of the VU University Medical Center, Amsterdam, The Netherlands (protocol number 2013/248).

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CHAPTER 5
The “Strengthen your ankle” program to prevent recurrent injuries. A randomized controlled trial aimed at long-term effectiveness.

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ABSTRACT

Objectives Recurrent ankle sprains can be reduced by a neuromuscular training program (NMT). The way NMT is delivered may influence the incidence of long term recurrent injuries, residual pain and disability.

Design This RCT with a follow-up of twelve months, evaluated whether the implementation method of a proven effective NMT program delivered by a mobile application or a written instruction booklet, resulted in differences in injury incidence rates, functional ankle disability/pain in the long term, assuming equal compliance – as in shown in previous research - with the eight-week intervention.

Methods 220 athletes with a history of ankle sprain were recruited for this RCT. 110 athletes were offered the freely available “Strengthen your ankle App” and the other 110 received a printed Booklet. Primary outcome measure was incidence density of ankle sprains. Secondary outcome measures were residual pain/disability and the individual cumulative number of ankle sprains during follow-up.

Results The incidence densities of self-reported ankle sprain recurrences were not significantly different between both groups (HR 1.06; 95% CI 0.76-1.49). Median FADI scores increased equally over time in both groups, indicating a lower rate of limitation and pain in both groups at follow-up. Neither FADI scores nor cumulative recurrent injuries were significantly different between groups.

Conclusion This study showed that the implementation method of a NMT program by using an App or a Booklet did neither lead to different injury incidence rates in the long term nor did it influence residual functional disability/pain. Assuming equal compliance during the eight-week intervention, both methods show similar effectiveness in twelve-month follow-up.

Trial registration
The Netherlands National Trial Register NTR 4027. The NTR is part of the WHO Primary Registries.
INTRODUCTION

Despite ongoing societal and scientific attention, sports injuries continue to pose a substantial health care problem. Although exercise is generally seen as contributing to overall health, the manifestation of a sport or physical activity related injury causes harm both from a personal as well as a societal viewpoint [1]. The ankle is the second most injured body part across all sports and activities, with an ankle sprain being the most common ankle injury [2]. In the Netherlands alone, in 2013, on a population of 17 million 480,000 people suffered from an ankle sprain due to sports [3]. Previous studies have shown the effectiveness of neuromuscular training programs [4]. Such programs require individuals to complete a multi-week exercise program that should be carried out multiple times a week. Although the effectiveness of such preventive programs has been shown in controlled studies, the majority of individuals involved were neither able nor willing to comply with the prescribed program. Performing only part of such preventive exercise programs has been shown to be ineffective in reducing the risk of an (recurrent) ankle sprain [5,6]. In recognition of the major problem that ankle sprains continue to pose for those involved in physical activities and sports, it is, therefore, of importance that available programs are enhanced in such a way that compliance with the exercise scheme is increased.

In order to increase compliance, it is crucial that the method of implementation is seen as attractive and has low barriers of use to the ones involved. The choice of implementation method may influence both compliance and, more importantly, the recurrence of sport injuries. A previous study has shown that during the actual course of an intervention program, there was no difference in compliance when a printed instruction Booklet was used when compared with a mobile application, and that during the course of the intervention program the number of recurrent injuries did not differ between both implementation methods [7]. However, difference in preventive effectiveness may be seen over a longer follow-up period, i.e. during a follow-up period beyond the actual intervention program. Consequently, the aim of the current study was to investigate whether delivering a proven effective neuromuscular training program through a Booklet or an App results in differences in recurrent ankle sprain incidence over a 12-month follow-up, under the condition of equal effectiveness and equal compliance/adherence across deliverance methods during the actual 8 weeks intervention program. A secondary aim was to investigate differences in pain and functional outcomes during daily activities over the 12 months of follow-up. The answer to these questions is of importance to further develop the methods of delivery of the neuromuscular training program in particular and injury prevention in general, which are both effective and attractive for those involved.

METHODS

This study was a randomised controlled trial. A detailed description of the study protocol has been published previously [8]. The Medical Ethics Committee (2013/248) of the VU University Medical Center Amsterdam (VUmc) the Netherlands approved the study design and informed consent procedure for this study. The trial is registered in the Netherlands Trial Registry (NTR4027).

From October 2013 to April 2014 physiotherapy and sport physician practices, national sport federations’ websites, digital newsletters and social media were used to recruit active
sports participants (athletes) between 18 and 70 years. To be included in the study athletes had to have incurred a self-reported ankle sprain within two months before inclusion into the study and had to have access to a mobile smart phone (either Android or iOS). When respondents had suffered a different injury in the same ankle in the preceding year (e.g., fracture of the ankle) they were considered non-eligible. The first author assessed all reported ankle sprains from the participants orally to confirm inclusion eligibility. The flow of participants is shown in Figure 1.

**Figure 1 | Flowchart of participant recruitment and follow-up**

Previous to the current study on the long-term effects, a study was carried out with the same study sample on the short-term effects. The primary outcome measure of this short-term study was compliance to the 8-week training programme. Therefore, sample size calculations were based upon the expected compliance rates and grounded on previously reported compliance rates to the same program [11]. Full compliance rates in the control group (Booklet) were expected to be around 25%. A doubling of this rate to at least 50% in the intervention group (i.e., the App group; see below) was considered to be clinically...
relevant. Based upon a beta of 0.90 and an alpha of 0.05, a total of 158 athletes was required, divided across both study groups. Assuming a dropout rate of 20%, a sample of 190 participants was calculated.

After participants had finished usual care for their ankle sprain treatment, and had returned the informed consent and baseline questionnaire, they were randomly assigned to one of two study groups; i.e. an App group and a written (print) materials only group (i.e. ‘Booklet group). Participants were allocated to the study groups through a random number generator. The App group was instructed to use the "Strengthen your Ankle" (in Dutch: "Versterk je Enkel") App on their mobile phone, which could be downloaded for free from either the App Store [9] or the Google Play store [10]. The Booklet group received a Booklet with the same NMT program on paper.

All participants received the same balance board (machU/ MSG Europe BVBA). Both the Booklet and the App contained the same NMT program that consisted of six different exercises to be performed during three sessions a week, for a period of eight weeks. Difficulty and load of the exercises were prescribed to increase every week. The NMT program has been shown to be cost-effective in reducing recurrent ankle sprain in previous trials [5,12]. The App provided the participant with an interactive exercise schedule, possibility for reminders, written instructions, and narrated video instructions on each exercise. The Booklet used pictures and written instructions to explain the exercises. During the eight weeks of the intervention, weekly questionnaires were sent to all participants. After the eight weeks these questionnaires were sent monthly for a further ten months. During these ten-month follow-up participants were no longer required to follow the NMT program. These monthly questionnaires included questions on recurrent injuries, exposure to sport activities and, pain and limitations as a result of the initial and/or recurrent ankle sprain. The study showed no differences in compliance with the intervention between the App-group and the Booklet-group during the eight weeks of the intervention programme [7].

An online baseline questionnaire was used to collect participants' information on physical characteristics, injury and sports history, use of preventive measures (tape, brace), and severity, received treatment and rehabilitation of the inclusion ankle sprain.

The primary outcome measure of the current study was incidence density of ankle sprains as measured by self-report during the twelve-month follow-up. Injury incidence density (IID) was defined as the number of recurrent ankle sprains per 1,000 hours of sports exposure. During the twelve-month follow-up, participants were asked monthly through online questionnaires about their hours of sports exposure and whether they had sustained an ankle sprain in the previous month. Ankle sprain recurrence was defined as a self-reported inversion moment of the same ankle, by which both a mere moment of inversion (giving way) as well as clinical ankle sprains were included. Self-reported recurrent ankle sprains were categorized by severity by looking at recurrences that had led to time-loss or costs. Time loss was defined as the discontinuity of (sport) activity and / or missing (part of) the next planned (sports) activity due to the recurrent ankle sprain [11]. Sprains that resulted in either direct or indirect costs were categorized as sprains leading to costs. These methods have been used previously in two comparable studies looking at the effectiveness of the NMT program to prevent recurrent ankle sprain [6,12].

Secondary outcome measure was the Functional Disability Ankle Index (FADI, Martin 1999) [12]. This index has been validated previously and has been used to describe pain at the
ankle and difficulty during daily activities [14,15]. The FADI consists of 26 items scored on a five-point Likert scale. The FADI was included in the monthly questionnaires. The index score was recorded as a percentage. A full score of 104 points resulted in a 100% score. The higher the FADI, the lower the rate of limitation and pain as a result of the ankle sprain. Twenty-two items questioned limitations on daily activities. Subjects rated the activity as no difficulty at all (4 points), slight difficulty (3 points), moderate difficulty (2 points), extreme difficulty (1 point), unable to do (0 points). Not applicable (N/A) was scored when the activity was limited by something other than the ankle sprain. If N/A was scored, this item was not included in the final score. For pain related items scores were: no pain (4 points), mild pain (3 points), moderate pain (2 points), extreme pain (1 point) and unbearable pain (0 points).

Another secondary outcome measure was the cumulative number of ankle sprains and/or injuries during the twelve months of follow-up from baseline, per participant. This secondary outcome measure was calculated by adding all recurrent injuries that were sustained during the twelve months of follow-up.

Mean baseline differences between the App and the Booklet group were determined using an independent samples t-test for continuous data (age, body weight, body height, exposure) and Fisher’s exact test (with Monte Carlo 95% confidence interval simulation due to small number of samples) for categorical data (level of sport, severity of ankle sprain, gender). Baseline measurements were based on the total number of participants (n=220) that were allocated to either one of the interventions.

Cox regression analyses compared risk of self-reported, time loss and cost recurrent ankle sprains between the groups. No significant difference between the incidence of recurrent injuries was found. Injury incidence analyses were checked for confounders and effect modifiers. During the first eight weeks of the study, all participants were questioned on their compliance with the exercise program. Performing at least 75% of all exercises was regarded as being compliant with the exercise program [6]. No confounders were found. As gender was found to be an effect modifier in the short term, separate results were presented for men and women [7].

A Mann-Whitney U test was used to calculate the differences between monthly FADI scores and cumulative injury recurrences between both groups.

All analyses were conducted according to the intention-to-treat principle and differences were considered significant with a significance level of 0.05.
RESULTS

A total of 220 athletes was recruited during the recruitment period October 2013 to April 2014. At baseline, both groups were comparable regarding all variables measured (Table 1).

Table 1 Baseline characteristics of the study population. Numbers are presented as percentage of the population (%), the median with corresponding range or as the mean with corresponding standard deviation (mean ± SD)

<table>
<thead>
<tr>
<th></th>
<th>Combined</th>
<th>App</th>
<th>Booklet</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants (n)</td>
<td>220</td>
<td>110</td>
<td>110</td>
<td></td>
</tr>
<tr>
<td>Number of males (n and %)</td>
<td>110 (50.0)</td>
<td>55 (50.0)</td>
<td>55 (50.0)</td>
<td>1.000</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>37.9 ± 13.4</td>
<td>37.6 ± 13.1</td>
<td>38.1 ± 13.7</td>
<td>0.741</td>
</tr>
<tr>
<td>Weekly sports exposure (hours and range)</td>
<td>3.0 (0-19.5)</td>
<td>3.0 (0-15.0)</td>
<td>3.0 (0-19.5)</td>
<td>0.791</td>
</tr>
<tr>
<td>Level of sport (n and %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competitive, international</td>
<td>9 (4.1)</td>
<td>2 (1.8)</td>
<td>7 (6.3)</td>
<td>0.311</td>
</tr>
<tr>
<td>Competitive, national</td>
<td>32 (14.5)</td>
<td>19 (17.3)</td>
<td>13 (11.8)</td>
<td></td>
</tr>
<tr>
<td>Competitive, regional</td>
<td>76 (34.5)</td>
<td>40 (36.4)</td>
<td>36 (32.7)</td>
<td></td>
</tr>
<tr>
<td>Recreational, organised</td>
<td>56 (25.5)</td>
<td>25 (22.7)</td>
<td>31 (28.2)</td>
<td></td>
</tr>
<tr>
<td>Recreational, unorganised</td>
<td>47 (21.2)</td>
<td>24 (21.2)</td>
<td>23 (20.9)</td>
<td></td>
</tr>
<tr>
<td>Contact sport (n and %)</td>
<td>136 (61.8)</td>
<td>68 (61.8)</td>
<td>68 (61.8)</td>
<td>1.000</td>
</tr>
<tr>
<td>Severity of inclusion sprain (n and %)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>91 (41.3)</td>
<td>47 (42.7)</td>
<td>44 (40.0)</td>
<td>0.666</td>
</tr>
<tr>
<td>Grade 2</td>
<td>64 (28.9)</td>
<td>34 (30.9)</td>
<td>30 (27.3)</td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>18 (8.0)</td>
<td>10 (9.1)</td>
<td>8 (6.9)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>48 (21.8)</td>
<td>19 (17.3)</td>
<td>29 (26.4)</td>
<td></td>
</tr>
<tr>
<td>Medically treated (n and %)</td>
<td>134 (61.0)</td>
<td>67 (61.0)</td>
<td>65 (59.0)</td>
<td>0.783</td>
</tr>
</tbody>
</table>
A total of 20,046 hours of sports participation was registered during the 12-month follow-up. In the App group the total exposure was 9,397 hours, whereas in the Booklet group total exposure was 10,648 hours. During 12 months follow-up, there were 139 recurrent ankle injuries: 70 in the App group and 69 in the Booklet group. Thirty-two injuries led to costs and 38 injuries to time loss. Table 2 shows the injury incidence densities of all recurrent injuries, those leading to time loss and those resulting in costs. Via Cox regression analysis no differences in injury incidence density were found between groups (p<0.05).

**Table 2** Injury incidence density (IID) of self-reported, time loss, and ankle sprain recurrences leading to costs (95% CI) per 1,000h of sports participation, as well as the Hazard Ratio (95% CI) derived from Cox regression analyses.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
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<th>Booklet</th>
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<tbody>
<tr>
<td></td>
<td>n IID</td>
<td></td>
<td>n IID</td>
<td></td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Self-reported</td>
<td>70 15.59 (11.94-19.24)</td>
<td>69 15.84 (12.10-19.58)</td>
<td>1.06 (0.76 - 1.49)</td>
<td></td>
</tr>
<tr>
<td>Time loss</td>
<td>13 1.50 (0.69 - 2.32)</td>
<td>25 2.71 (1.65 - 3.77)</td>
<td>0.55 (0.82 - 1.09)</td>
<td></td>
</tr>
<tr>
<td>Costs</td>
<td>16 1.96 (1.00-2.92)</td>
<td>16 1.85 (0.95-2.76)</td>
<td>1.13 (0.56 - 2.27)</td>
<td></td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported</td>
<td>34 9.88 (6.56-13.20)</td>
<td>27 8.74 (5.00-12.48)</td>
<td>1.12 (0.68-1.87)</td>
<td></td>
</tr>
<tr>
<td>Time loss</td>
<td>8 1.49 (0.46-2.52)</td>
<td>11 3.65 (1.49-5.81)</td>
<td>0.51 (0.20-1.29)</td>
<td></td>
</tr>
<tr>
<td>Costs</td>
<td>9 1.76 (0.61-2.9)</td>
<td>6 1.99 (0.40-3.58)</td>
<td>1.17 (0.41-3.30)</td>
<td></td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self-reported</td>
<td>36 34.25 (23.06-45.44)</td>
<td>42 20.99 (14.57-27.42)</td>
<td>1.09 (0.70-1.72)</td>
<td></td>
</tr>
<tr>
<td>Time loss</td>
<td>5 1.52 (0.19 - 2.85)</td>
<td>14 2.49 (1.19-3.80)</td>
<td>0.51 (0.18-1.44)</td>
<td></td>
</tr>
<tr>
<td>Costs</td>
<td>7 2.30 (0.60-4.00)</td>
<td>10 1.61 (0.61-2.61)</td>
<td>1.04 (0.39-2.77)</td>
<td></td>
</tr>
</tbody>
</table>
Median FADI scores increased over time from 92.9 (62.0-100.0) at baseline to 100 (57.6-100.0) at 12 months’ follow-up in the App group and from 93.8 (57.1-100.0) at baseline to 100 (78.9-100.0) at 12 months’ follow-up in the Booklet group, respectively. In none of the follow-up months FADI scores were significantly different between groups. From the 3rd month onwards, after the training programme had been completed, participants experienced little pain and or disability from their ankle injury. During the final months of the follow-up, pain and disability scores did, on average, not increase.

A total of 58 participants reported more than one self-reported recurrent ankle injury during the follow up. Twelve participants in the App group and 20 in the Booklet group suffered from two ankle sprains in the 12-months follow-up; another 4 (App) and 9 (Booklet) participants recurred three ankle sprains, 4 (App) and 2 (Booklet) participants dealt with four recurrent ankle sprains, and in both groups 3 participants recurred five recurrent ankle sprains. Finally, one participant in the App group had had six self-reported ankle sprains within the twelve months. A total of 11 participants suffered two injuries leading to costs; 6 in the App group and five in the Booklet group. A further 7 participants dealt with two injuries leading to time loss, 3 in the App group and 4 in the Booklet group. The difference in total number of injuries leading to time loss between both groups reached significance (p<0.04), with no significant difference between both total number of recurrent injuries (p>0.58) and total number of injuries leading to costs (p<0.98).
The persistent existence of sport-related injuries has provided researchers and health professionals with a continuing challenge to develop and improve effective interventions [3]. To stimulate injured athletes to comply with such interventions, the programs implemented should be attractive with low barriers to use [1]. In the present-day society, where mobile and tablet usage is rising, E-health is thought to provide new opportunities to increase compliance to effective intervention programs.

Mobile applications allow for new features, such as verbal instructions, video's showing the correct execution of exercises and a calendar function to remind users to do the exercises as advised. As our previous study has shown, an App did not lead to better compliance, compared to the traditional way of delivering an intervention via printed material in the shape of a Booklet. However, the previous study did not address effects on injury incidence over a twelve-month period, as this study did. This study showed, during the follow-up of twelve months, neither a significant difference in injury incidence density between the two groups nor a difference in injuries leading to costs or time loss. In addition, the FADI scores increased equally in both groups during follow-up and reached a ceiling effect after three months. Hereafter, pain and disability scores did not increase during the remainder of the follow-up. The cumulative number of recurrent injuries did not show a significant difference between the App and the Booklet group.

These results do not, by any means, show that the use of E-health is of no use in sport injury prevention. It does show that the use of mobile applications is as effective as the use of more traditional printed instructions. Both methods of implementation have received an update after completing our study. This update aims to increase the attractiveness and usability and this may lead to even better compliance/adherence rates, thus potentially leading to even better outcomes. It is promising that the compliance in our study with the intervention showed an increase, as compared to previous studies looking at the same neuromuscular training program but with an older, simpler version of the booklet [5,12]. In these studies, compliance with the program was lower during the eight weeks of exercises – respectively 23% [5] and 45% of the athletes had high compliance with the intervention – as compared to 65% in the study using the new material [12]. With respect to recurrent ankle injuries, the previous two studies reported an injury incidence density of 1.86 per 1000 h of sport; 95% 1.37-2.34 and 2.51 per 1000 h of sport; 95% 1.59-3.42 [5,12]. Although these injury densities are vast lower than the ones reported in the current study (15.59 per 1000 h of sport; 95% 11.94-19.24) for the App group and (15.58 per 1000 h of sport; 95% 12.10-19.58) in the Booklet group, this should be interpreted as a difference due to a difference in injury definition as the current study also included ‘giving way’ as a component of the definition of recurrent ankle injury. Additionally, more than half of the recurrent self-reported injuries (46/70 in the App group and 47/69 in the Booklet group) in the current study occurred during the first two months of the study, in which the participants were still following the exercise program. The lesser half of all injuries was spread over the ten-month follow-up period. It is unknown how the distribution of recurrent injuries developed over time in the other two studies.

It would be of great interest to see if the simultaneous and combined use of both methods can further increase compliance and hence contribute to effective sport injury prevention. When both methods of implementation can be used simultaneously, athletes involved have a diversity of means to use. This allows athletes to choose the method that is most
convenient at a certain moment in time and/or that is in line with their personal preferences.
The results from this study can be seen as an important contribution to the scientific community. Where for the majority of available Apps the App content is not evidence-based, the “Strengthen your Ankle” App uses a proven effective intervention [5,16].

In the twelve months of follow-up, athletes were contacted monthly to assess their recurrent injuries and FADI scores. In the questionnaires used, they were also asked whether they had continued using the App and/or the Booklet. It is possible that being part of this study protocol has influenced their use of the intervention. Therefore, in a real-life situation, without the stimulus of this research, athletes might be less likely to continue the exercises and as a result develop more recurrent injuries.

CONCLUSION

This study showed that the method of implementing the exercises by using an App or a Booklet did not lead to different injury incidence rates in the long term nor did it influence residual functional disability or pain. Assuming equal compliance during the eight-week intervention – as is shown in previous research - both methods showed similar effectiveness in a twelve-month follow-up. This indicates that both methods can be used interchangeably to reduce the risk of recurrent ankle sprains.
PRACTICAL IMPLICATIONS

- A proven effective neuromuscular training programme can be delivered both in a mobile application as in a printed instruction booklet.

- Both methods of implementation can be used interchangeably to reduce recurrent ankle sprains in the long term.

- Number of recurrent ankle injuries, residual pain/disability and cumulative number of recurrent ankle sprains are similar with both implementation methods.

ACKNOWLEDGEMENTS

We would like to thank the following partners for their collaboration and recruitment of study participants: Royal Dutch Society for Physical Therapy (KNGF), Dutch Society for Physical Therapy in Sports (NVFS), Dutch College of General Practitioners (NHG), Dutch Sports Medicine Society (VSG), Dutch Olympic Committee (NOC*NSF), Zilveren Kruis Achmea (ZKA), and Disporta.
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CHAPTER 6
Preventing recurrent ankle sprains: Is the use of an App more cost-effective than a printed Booklet? Results of a RCT.

Miriam van Reijen
Ingrid Vriend
Willem van Mechelen
Evert Verhagen

Scandinavian Journal of Medicine and Science in Sports 2017
Digital object identifier (doi): 10.1111/sms.12915
ABSTRACT

Objectives Recurrent ankle sprains can be reduced by following a neuromuscular training (NMT) program via a printed Booklet or a mobile application. Regarding the high incidence of ankle sprains, cost-effectiveness regarding implementation can have a large effect on total societal costs.

Design In this economic analysis we evaluated whether the method of implementing a proven effective NMT program by using an App or a Booklet resulted in differences in injury incidence rates leading to costs and hence to differences in cost-effectiveness.

Methods 220 athletes with a previous ankle sprain were recruited for this randomised controlled trial with a follow-up of twelve months. Half of the athletes used the freely available ‘Strengthen your ankle’ App and the other half received a printed Booklet. After the eight-week program athletes were questioned monthly on their recurrent injuries. Primary outcome measures were incidence density of ankle injury and incremental cost-effectiveness ratio (ICER).

Results During follow-up 31 athletes suffered from a recurrent ankle sprain that led to costs resulting in a Hazard Ratio of 1.13 (95% CI: 0.56-2.27). The incremental cost-effectiveness ratio (ICER) of the App group in comparison with the Booklet group was €-361.52. The CE plane shows that there was neither a difference in effects nor in costs between both intervention methods.

Discussion This study showed that the method of implementing the NMT program by using an App or a Booklet led to similar cost-effectiveness ratios and the same occurrence of recurrent injuries leading to costs. Both the App and the Booklet can be used to prevent recurrent ankle injuries, showing no differences in (cost-)effectiveness at 12 months’ follow-up.

Trial registration

The Netherlands National Trial Register NTR 4027. The NTR is part of the WHO Primary Registries.

Contributors

EV (e.verhagen@vumc.nl) conceived the research idea, MVR (m.vanreijen@vumc.nl, @miriamvanreijen) and EV have written the protocol, MVR has screened and included patients, performed data analyses and is the main author. IV (i.vriend@vumc.nl) and WVM (w.vanmechelen@vumc.nl) contributed to ideas in the protocol. All authors have read and commented on the draft version and approved the final version of the manuscript.
INTRODUCTION

There is no discussion whether physical activity and exercise can benefit the individual. The right sort and amount of physical activity and exercise can increase an individual's longevity, reduce the risk of numerous diseases and allow for feelings of joy, friendship and relaxation [1-4]. There is no doubt that these individually experienced benefits also influence the wellbeing of society as a whole [5]. However, exercise does bring about burden and related costs to the individual as well as society in the form of sports and exercise related injuries [6]. In 2013 in the Netherlands alone, a total of 4.5 million sport and exercise related injuries occurred on an active population of 12 million. Two fifth of those injuries (1.9 million) required medical treatment. It was calculated that this resulted in a total cost of €520 million [7].

Ankle sprains are the most common sports and exercise related injury. In addition to the direct burden of such injuries, there is an increased risk of incurring recurrent ankle sprain and the risk of chronic residual pain [8-11]. Both the high incidence of ankle sprain, the high risk of recurrence, as well as the resulting societal costs justify preventive efforts.

To address the prevention of recurrent ankle injuries numerous interventions have been developed. Examples of interventions are predominantly focused on using supportive material (e.g. tape and brace) and or the strengthening of the ankle by exercises [12,13]. An intervention that has been shown repeatedly to reduce recurrent ankle injury risk to the level of someone who has never sprained his/her ankle is an eight-week neuromuscular training program [14]. This program has been shaped in the ‘Strengthen your Ankle’ training program and has been implemented in The Netherlands both via a printed instructional Booklet as well as via a mobile application. Previous studies have shown that both methods of implementing this neuromuscular training program are equally effective in enabling compliance with the program, as in reducing the number of self-reported recurrent injuries [15,16]. Although equally effective on these outcomes, cost-effectiveness may still differ. As both methods require substantial development and implementation costs, it is important to evaluate whether the costs and the associated preventive effect of the App and the Booklet justify their widespread use. A number of studies have already addressed the importance of cost-effectiveness and allow for comparisons of different methods. As a result, accurate analyses have been developed that determine the cost-effectiveness of the current intervention [14,17]. The present study follows the line of these studies and evaluates the cost-effectiveness of the Booklet and the App in preventing recurrent ankle sprains over a 12 month follow up.

METHODS

This study, evaluating cost effectiveness of two methods used to implement the neuromuscular ‘Strengthen your Ankle’ program was part of a larger randomized controlled trial of which the design has been published before [18]. Briefly, active sports participants (athletes) who had incurred a self-reported ankle sprain within the past two months were randomized to one of two study groups via a random number generator. The Medical Ethics Committee (2013/248) of the VU University Medical Center, Amsterdam
(VUmc) the Netherlands, had approved the study design and informed consent procedure for this study. The trial is registered in the Netherlands Trial Registry (NTR4027).

Inclusion was held between October 2013 and April 2014 via physiotherapy and sports physician practices, national sport federations’ websites, digital newsletters and open invitation via social media, the Internet and written media. To be included in the study active sports participants (between 18 and 70 years) had to have sustained an ankle sprain within the past two months and had to have access to a mobile smart phone (either Android or iOS). When respondents had suffered another injury in the same ankle in the preceding year (e.g., fracture of the ankle) they were considered non-eligible. All reported ankle sprains were assessed by phone by the main author to confirm inclusion eligibility. The flow of participants can be found elsewhere [18].

Sample size was based on compliance to the eight-week training program, which was the main outcome of the primary short-term (i.e. during the 8 weeks of the trial) effectiveness study [15]. It was expected that 25% of the participants would be fully compliant with the training program. A doubling of this compliance rate was considered clinically relevant. Based upon a beta of 0.90 and an alpha of 0.05, a total of 158 athletes was required, i.e. 74 per group. Previous comparable studies have shown a dropout rate during a 12 months’ follow-up of about 20% [14]. This means that a sample of 190 participants was required at baseline, i.e. 95 per group. The study was approved by the medical ethics committee of the VU University Medical Centre, Amsterdam, The Netherlands (protocol number 2013/248) and patient consent was obtained.

Participants in both groups received the same balance board (machU, MSG Europe BVBA) and the same neuromuscular training (NMT) program, which consisted of six different exercises to be performed during three sessions a week, for a period of eight weeks. The printed instruction Booklet showed pictures of the exercises, an eight-week training schedule and written instructions. The App provided the participants with both written, visual and verbal instructions and included a calendar function.

The App group was instructed to use the ‘Strengthen your Ankle’ App on their mobile phone, which could be downloaded for free from either the App Store or the Google Play Store [19,20]. The Booklet group received a Booklet with the same NMT program, but on paper. Both groups were questioned weekly – with online questionnaires - on their compliance with the program, as well as any incurred recurrent ankle injuries during the 8 weeks of the neuromuscular training program. Thereafter participants were questioned monthly on incurred recurrent ankle injuries, for a total follow-up of ten months.

When an athlete suffered from a recurrent injury, a cost diary had to be completed weekly until full recovery. This cost diary registered all absence from study, school and (un)paid work, as well as health care utilization, and the purchase of medical equipment such as braces, tape or medication. This method has been used in previous studies to determine cost-effectiveness of the same NMT programme [14,17].

Ankle sprain recurrence was defined as a self-reported inversion moment of the same ankle, by which both a mere moment of inversion as well as clinical ankle sprains were included. Self-reported recurrent ankle sprains were further categorized to severity by looking at recurrences that led to time-loss or costs. Time loss was defined as the discontinuity of (sport) activity and / or missing (part of) the next planned (sports) activity due to the recurrent ankle sprain [21]. Sprains that resulted in either direct or indirect costs were categorized as sprains leading to costs. This method has been used previously in two
comparable studies looking at the effectiveness of the NMT program to prevent recurrent ankle sprain [14, 17].

At baseline, a questionnaire was sent to all participants to question physical characteristics, injury and sports history, use of preventive measures (tape, brace), and severity, received treatment and rehabilitation of the inclusion ankle sprain. Costs related to the use of the ‘Strengthen your ankle’ App and the printed instruction Booklet included the use for the included material costs (the balance board) and for the development of the App or Booklet, the time spent conducting the program (patient time costs), as well as the costs that were incurred due to a recurrent ankle sprain (indirect and direct health care costs) during the twelve months of follow-up. Table 1 shows the cost categories that were used in this study.
The development costs of the App were calculated by Veiligheid.NL and included the recording of instructional videos, the costs of design, the costs for publication in both the Google Play Store and the App Store and testing of both the iPhone and Android versions of the app. Development costs were then divided by the total number of downloads as registered in December 2013 (n=39,350), when follow-up of this study had ended. The development of the booklet included the costs for development, printing, transportation and storage of the booklets. These total costs are divided by the total number of printed booklets (n=112,500) by the end of 2013.

Patient time was considered as unpaid work, estimated at a shadow price of €14,00 per hour [22]. Time spent on the training program could be determined very accurately, as all participants kept a detailed record of which exercises they performed each week during the

Table 1 | Costs applied in the economic analysis

<table>
<thead>
<tr>
<th>Cost of the App group (per athlete)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance board</td>
<td>€14.00</td>
</tr>
<tr>
<td>Cost per downloaded App</td>
<td>€1.61</td>
</tr>
<tr>
<td>Patient time (maximum)</td>
<td>€168.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cost of the Booklet group (per athlete)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance board</td>
<td>€14.00</td>
</tr>
<tr>
<td>Cost per printed Booklet</td>
<td>€0.26</td>
</tr>
<tr>
<td>Patient time (maximum)</td>
<td>€168.00</td>
</tr>
</tbody>
</table>

Direct health care costs

<table>
<thead>
<tr>
<th>General practitioner (20 min per visit)</th>
<th>€33.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner (telephone consult)</td>
<td>€17.00</td>
</tr>
<tr>
<td>Physical therapist (30 min per visit)</td>
<td>€33.00</td>
</tr>
<tr>
<td>Medical specialist (per visit)</td>
<td>€52.00</td>
</tr>
</tbody>
</table>

Indirect health care costs

<table>
<thead>
<tr>
<th>Absenteeism from paid work - men (per day)</th>
<th>€37.90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absenteeism from paid work - women (per day)</td>
<td>€31.60</td>
</tr>
<tr>
<td>Absenteeism from unpaid work (per hour)</td>
<td>€14.00</td>
</tr>
</tbody>
</table>

a: Price according to Dutch guidelines [22]
eight-week of the training program. From this it could be deducted how much patient time was actually involved. With full compliance, the complete program requires 3 x 30 minutes of patient time per week.

Associated health care costs, standard prices for health care utilization and the costs of medication and medical equipment were based on the prices as recommended by the Royal Dutch Society of Pharmacy [22]. Finally, costs for absenteeism from school, study and/or (un)paid work were included. Unpaid work was estimated at a shadow price of €14,00 per hour, paid work was determined by using the friction method. This method assumes that all work is replaceable and that associated societal costs are only made during the time it takes to find replacement [17]. It is recommended that the average period to find replacement, and thus the recommended friction period, is 85 days [22]. All prices were standardized to the year 2015.

From the online questionnaires, the injury incidence density (IID) and corresponding 95% confidence interval (95% CI) was calculated as the number of recurrent ankle sprains per 1,000 hours of exposure [17,23]. From 30 of the 31 participants (97%) that had sustained a recurrent injury during follow-up period, a cost diary was retrieved. One participant failed to send information on possible costs that were made after the recurrent injury, although they stated to have made costs. The participant from which data was missing was from the Booklet group. Given the limited amount of missing data, imputation techniques were not used.

To calculate 95% CIs around mean costs, cost differences and mean patient time and patient time differences, nonparametric bootstrapping was used with 1,000 replications. Cox regression analyses compared risk of self-reported, time loss and cost recurrent ankle sprains between both groups.

In addition, the Incremental Cost-Effectiveness Ratio (ICER) was calculated, using the Booklet group as the reference group [24]. The ICER represents the incremental costs of the training program using the App to prevent one ankle sprain recurrence, in comparison to the program followed using the Booklet. The ICER can be calculated as: \((\text{C}_b-\text{C}_a)/(\text{E}_b-\text{E}_a)\) = \(\Delta C/\Delta E\), in which \(\text{C}_b\) = mean costs in the Booklet group, \(\text{C}_a\) = mean costs in the App group, \(\text{E}_b\) = mean effects in the Booklet group and \(\text{E}_a\) = mean effects in the App group. The uncertainty that results from this ICER was plotted in a cost-effectiveness plane, using nonparametric bootstrapping with 1,000 replications. All analyses were conducted according to the intention-to-treat principle and differences were considered significant with a significance level of .05.

RESULTS

A total of 220 athletes was recruited during the recruitment period October 2013 to April 2014. At baseline, both groups had no significant differences regarding all variables measured. Table 2 shows the baseline characteristics of the study population.
Table 2 Baseline characteristics of the study population. Numbers are presented as percentage of the population (%), the median with corresponding range or as the mean with corresponding standard deviation (mean ± SD).

<table>
<thead>
<tr>
<th></th>
<th>Combined</th>
<th>App</th>
<th>Booklet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants (n)</td>
<td>220</td>
<td>110</td>
<td>110</td>
</tr>
<tr>
<td>Number of males (%)</td>
<td>110 (50.0%)</td>
<td>55 (50.0%)</td>
<td>55 (50.0%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>37.9 ± 13.4</td>
<td>37.6 ± 13.1</td>
<td>38.1 ± 13.7</td>
</tr>
<tr>
<td>Weekly sports exposure at inclusion (hours)</td>
<td>3.0 (0-19.5)</td>
<td>3.0 (0-15.0)</td>
<td>3.0 (0-19.5)</td>
</tr>
<tr>
<td>Contact sport (%)</td>
<td>61.8%</td>
<td>61.8%</td>
<td>61.8%</td>
</tr>
<tr>
<td>Severity of inclusion sprain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>41.3%</td>
<td>42.7%</td>
<td>40.0%</td>
</tr>
<tr>
<td>Grade 2</td>
<td>28.9%</td>
<td>30.9%</td>
<td>27.0%</td>
</tr>
<tr>
<td>Grade 3</td>
<td>8.0%</td>
<td>9.1%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Unknown</td>
<td>21.8%</td>
<td>17.3%</td>
<td>26.1%</td>
</tr>
<tr>
<td>Medically treated (%)</td>
<td>61.0%</td>
<td>61.0%</td>
<td>61.0%</td>
</tr>
</tbody>
</table>

During the twelve-month follow-up period, there were 139 self-reported recurrent injuries. Of these injuries, 38 led to time loss (13 in the App group and 25 in the booklet group), and 31 led to costs (16 in the App group and 15 in the Booklet group). Table 3 shows the IID of all recurrent injuries during the twelve months of follow up, injuries leading to time loss and injuries leading to costs.
Table 3 Injury Incidence Densities (IID) and accompanying Hazard Ratios of all self-reported recurrent injuries, injuries leading to time loss and injuries leading to costs.

<table>
<thead>
<tr>
<th></th>
<th>App (n=110)</th>
<th>Booklet (n=110)</th>
<th>Hazard Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent injuries (IID)</td>
<td>15.59</td>
<td>15.84</td>
<td>0.94</td>
</tr>
<tr>
<td></td>
<td>(95% CI: 11.94-19.24)</td>
<td>(95% CI: 12.10-19.58)</td>
<td>(95% CI: 0.76-1.49)</td>
</tr>
<tr>
<td>Recurrent injuries leading to time loss</td>
<td>0.82</td>
<td>2.36</td>
<td>0.55</td>
</tr>
<tr>
<td></td>
<td>(95% CI: −0.30 - 2.00)</td>
<td>(95% CI: 0.50 - 4.20)</td>
<td>(95% CI: 0.28 - 1.09)</td>
</tr>
<tr>
<td>Recurrent injuries leading to costs</td>
<td>1.96</td>
<td>1.85</td>
<td>1.13</td>
</tr>
<tr>
<td></td>
<td>(95% CI: 1.00-2.92)</td>
<td>(95% CI: 0.95-2.76)</td>
<td>(95% CI: 0.56-2.27)</td>
</tr>
</tbody>
</table>

Median ± interquartile range of overall time spent on the exercise program was 600 ± 307 minutes. In the App group the mean overall time spent on the exercise program was 547 ± 278 minutes and in the Booklet group 547 ± 278 minutes. The overall time was not significantly different between both groups. The total cost per athlete was calculated as the sum of patient time, direct health care costs and indirect health care costs (Table 4). There was an overall non-significant cost difference of €0.65 per athlete between the App and Booklet group, in favour of the App. There was a total non-significant cost difference of €7.91 (95% CI €-77.95 - €85.69) per injured athlete between the App and the Booklet group, in favour of the Booklet.
Table 4: Mean and total Costs (€) per athlete and per injured athlete during 1-year follow-up. Values are expressed as mean (95% confidence interval). Cost differences are calculated with the App group as the reference.

<table>
<thead>
<tr>
<th>Costs per athlete (€)</th>
<th>App</th>
<th>Booklet</th>
<th>Mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 110</td>
<td>n= 110</td>
<td></td>
</tr>
<tr>
<td>Intervention materials</td>
<td>€15.61</td>
<td>€14.26</td>
<td>€1.35</td>
</tr>
<tr>
<td>Patient time costs</td>
<td>€123.07</td>
<td>€128.68</td>
<td>€-5.61</td>
</tr>
<tr>
<td></td>
<td>(€113.29 - €131.14)</td>
<td>(€118.33 - €138.12)</td>
<td>(€-5.15 - €7.58)</td>
</tr>
<tr>
<td>Material for recovery (i.e. brace, tape)</td>
<td>€5.41</td>
<td>€2.19</td>
<td>€3.22</td>
</tr>
<tr>
<td></td>
<td>(€1.41 - €10.33)</td>
<td>(€0.43 - €4.31)</td>
<td>(€-1.49 - €8.13)</td>
</tr>
<tr>
<td>Direct health care costs</td>
<td>€11.93</td>
<td>€6.66</td>
<td>€5.27</td>
</tr>
<tr>
<td></td>
<td>(€3.67 - €23.63)</td>
<td>(€1.77 - €12.36)</td>
<td>(€-5.76 - €17.43)</td>
</tr>
<tr>
<td>Indirect health care costs (productivity loss)</td>
<td>€15.18</td>
<td>€23.04</td>
<td>€-7.86</td>
</tr>
<tr>
<td></td>
<td>(€1.13 - €38.45)</td>
<td>(€0.76 - €60.01)</td>
<td>(€-56.45 - €27.67)</td>
</tr>
<tr>
<td>Total</td>
<td>€171.20</td>
<td>€173.29</td>
<td>€-2.09</td>
</tr>
<tr>
<td></td>
<td>(€147.15 - €204.35)</td>
<td>(€148.20 - €212.44)</td>
<td>(€-51.32 - €48.74)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Costs per injured athlete (€)</th>
<th>n=70</th>
<th>n=69</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention materials</td>
<td>€15.61</td>
<td>€14.26</td>
<td>€1.35</td>
</tr>
<tr>
<td>Patient time costs</td>
<td>€134.78</td>
<td>€128.20</td>
<td>€6.58</td>
</tr>
<tr>
<td></td>
<td>(€125.12 - €143.92)</td>
<td>(€117.43 - €139.00)</td>
<td>(€-7.75 - €20.26)</td>
</tr>
<tr>
<td>Material for recovery (i.e. brace, tape)</td>
<td>€8.51</td>
<td>€3.51</td>
<td>€5.00</td>
</tr>
<tr>
<td></td>
<td>(€2.33 - €16.05)</td>
<td>(€0.80 - €7.29)</td>
<td>(€-2.09 - €12.62)</td>
</tr>
<tr>
<td>Direct health care costs</td>
<td>€18.74</td>
<td>€10.68</td>
<td>€8.06</td>
</tr>
<tr>
<td>Indirect health care costs (productivity loss)</td>
<td>€23.86</td>
<td>€36.94</td>
<td>€-13.08</td>
</tr>
<tr>
<td></td>
<td>(€1.36 - €61.37)</td>
<td>(€1.44 - €94.59)</td>
<td>(€-95.65 - €48.00)</td>
</tr>
<tr>
<td>Total</td>
<td>€201.50</td>
<td>€193.59</td>
<td>€7.91</td>
</tr>
<tr>
<td></td>
<td>(€163.91 - €257.34)</td>
<td>(€154.43 - €252.70)</td>
<td>(€-77.95 - €85.69)</td>
</tr>
</tbody>
</table>

The incremental cost-effectiveness ratio (ICER) of the App group in comparison with the Booklet group was €-361.52, based on a difference in the mean cost €-3.29 and a difference in the mean effects of 1%. This means that prevention of 1 ankle sprain recurrence in the App group is associated with €361.52 cost savings per prevented recurrent ankle sprain.
Figure 1 shows the cost-effectiveness (CE) plane for differences in the recurrence of ankle sprains during the twelve months of follow-up for the Booklet group versus the App group. There was neither a difference in effects nor in costs between both intervention methods, as for the Booklet group only 38% was in the dominant southeast quadrant (indicating more effect) and 30% was in the southwest quadrant (indicating higher costs).

In a sensitivity analysis, we calculated the ICER when the patient time costs were disregarded from the analysis. The ICER of the Booklet group in comparison with the App group, the incremental cost-effectiveness ratio (ICER) was €755.31, based on a difference in the mean cost of €6,87 and a difference in mean effects of 1%. This means that, when patient time is not taken into account, prevention of 1 ankle sprain recurrence in the Booklet group is associated with €755.31 cost savings per prevented recurrent ankle sprain. Figure 2 shows the CE plane for differences in the recurrence of ankle sprains during the twelve months of follow-up for the Booklet group versus the App group.
Figure 2 Cost-effectiveness plane after the exclusion of patient time, presenting cost-effect pairs estimated by using bootstrapping (1,000 samples) for the difference in ankle sprain recurrence risk between the App group and the Booklet group. Each dot represents one bootstrapped cost-effect pair the difference in costs and effects of the App group compared to the Booklet group. The outcomes of the samples are spread over the four quadrants, with only 12% of the bootstrapped cost-effect pairs in the south-east ‘dominant’ quadrant.

DISCUSSION

Cost-effectiveness studies in sports injury prevention are rare. So far, only a handful of studies has performed such an analysis [14,17,25-28]. The 2014 study by Janssen was the compared two different treatment: the practice of using a brace in combination with neuromuscular training was compared to NMT and bracing alone. Compared to the current study, using the same NMT programme, the patient time costs for the NMT group as reported by Janssen et al. 2014 were considerably lower due to a lower compliance rate. Whereas only 45% of the patients in the 2014 study were seen as highly compliant, more than 70% of the patients in the current study reached high compliance (i.e. performing more than two thirds of all prescribed exercises). The use of either the Booklet or the App seems to be more accepted in the sports community and the updated versions of both methods are likely more attractive. The difference in compliance and hence patient time costs between this and the 2014 study is reflected in the different total cost per athlete (€171.52 in the current versus €135.26 for NMT group in the 2014 study). Costs for the combination group (€163.60) were similar due to high intervention costs (brace). The intervention material costs of the App were based on the knowledge that the App was downloaded a total of 39,350 times at the time of analyses. This number is increasing steadily, as more people are aware of the existence and effectiveness of the App. And thus, with time, the intervention costs associated with the App will decrease. The costs for printing the Booklet will remain the same, with no influence of the number printed. The
App is more than twice as expensive as the Booklet, and it is not likely that both methods will have the same price per unit in the future. The App has to be downloaded another 204,026 times to have the same price per unit as the printed Booklet. However, as a downloaded App can be updated, new prints are necessary as soon as an updated Booklet will be available.

Another methodological consideration is that athlete compliance has steadily increased over the last few years. NMT is now widely accepted as an effective method to reduce recurrent ankle sprains. It is likely that a number of athletes have already performed some sort of NMT before participating in this study. This might argueable reduce the initial risk of developing a (recurrent) ankle sprain.

**PERSPECTIVE**

This study evaluated the cost-effectiveness of an intervention to prevent the recurrence of ankle sprains delivered through an App versus the same intervention delivered through a Booklet. As is shown in previous research [15,16] the use of either the App or the Booklet show similar outcomes, both in the short and in the long run. Not only did both methods result in comparable compliance rates during the eight weeks of the training programme, both methods also led to comparable ankle sprain recurrence rates on the short (eight weeks) as well as long term (one-year). Adding the results from this cost-effectiveness study, in which it was found that the costs associated with both intervention delivery methods were not significantly different, it can be argued that both the App and the Booklet can be used successfully, and with the same cost efficiency, to reduce recurrent ankle sprains. The NMT program, in both methods of implementation, has the potential to rigorously reduce the currently high total societal costs of ankle sprain treatment.

**Competing interests**

The authors declare no competing interest. VeiligheidNL has provided the mobile App. However, this App is available for free.

**ACKNOWLEDGEMENTS**

We would like to thank the following partners for their collaboration and recruitment of study participants: Royal Dutch Society for Physical Therapy (KNGF), Dutch Society for Physical Therapy in Sports (NVFS), Dutch College of General Practitioners (NHG), Dutch Sports Medicine Society (VSG), Dutch Olympic Committee (NOC*NSF), Zilveren Kruis Achmea (ZKA), and Disporta.
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CHAPTER 7
Evidence based ankle sprain prevention in your pocket? A mixed methods approach on user's perspectives, opportunities and barriers of the Strengthen your ankle app.
ABSTRACT

Introduction The "Strengthen your ankle" neuromuscular training (NMT) program has been thoroughly studied in the past 8 years. This process evaluation is part of a RCT that examined both the short and long-term effectiveness of this particular program. Although it was shown previously that the program – both available in a printed Booklet and a mobile App - is able to effectively reduce the number of recurrent ankle sprains, from the short and long-term studies it was concluded that participants’ compliance with the program is an ongoing challenge.

Objective This process evaluation explored participants’ opinions regarding both methods of delivery, using the RE-AIM (Reach Effectiveness Adaptation Implementation Maintenance) Framework to be able to identify barriers and challenges to program compliance. While Reach, Effectiveness and Adaptation where subject of previous study, this paper focusses on the Implementation and Maintenance phase.

Methods Semi-structured interviews and online questionnaires were analysed using qualitative content analysis. Fisher's exact, \( \chi^2 \) and t-tests assessed differences in quantitative survey responses among groups. Interviews were assessed by thematic analysis which identified key themes.

Results Whilst there was no significant difference in perceived simplicity, usefulness and liking of the exercise during the eight weeks of the NMT program, semi-structured interviews showed that 14/16 participants agreed that an App would be of additional benefit over a Booklet. After twelve months’ follow-up, when asked how they evaluated the overall use of the App or the Booklet, users of the App gave a mean score of (mean ± sd) 7.7±0.99 versus a mean score of 7.1±1.23 for the users of the Booklet. This difference in mean score was significant (p=0.006).

Conclusions Although both the App and the Booklet show high user satisfaction, users of the App were significantly more satisfied. Semi-structured questionnaires allowed users to address issues they would like to improve in future updates. Including a possibility for feedback and postponement of exercises, an explanation of the use of specific exercises and possibly music can further improve the contentment of the program and hence might lead to increased compliance.

Trial registration

The Netherlands National Trial Register NTR 4027. The NTR is part of the WHO Primary Registries.
INTRODUCTION

Injuries, due to participation in sports and physical activities, are prevalent. Internationally, ankle sprains are one of the most common musculoskeletal injuries [1]. In particular, indoor and court sports have shown high incidences of ankle sprains with up to 7 injuries per 1000 hours of participation [2]. Generally considered a “minor” injury, ankle sprains pose a significant risk for long-term secondary complaints like instability and chronic pain [3]. For the prevention of acute lateral ankle sprains, numerous effective strategies have been developed and evaluated for their cost-effectiveness [2].

One of the many available interventions that has been shown to be effective in reducing the risk of recurrent ankle sprains, as well as protecting against secondary complaints, is neuromuscular training (NMT) [3-5]. Multiple variations of such training programs have been evaluated [6-8], including the “Strengthen Your Ankle” program (NMT). The “Strengthen Your Ankle” program consists of 6 exercises that are performed 3 times a week, over 8 weeks. Multiple trials have indicated that this program can be effective in reducing the injury incidence density [9,10] as well as being cost-effective [10,11]. Despite the proven value of the program in preventing recurrent injury risk, compliance with this and other NMT programs is an ongoing challenge [3]. Sufficient compliance with NMT programs is essential for successful prevention of ankle sprains [12]. Consequently, a free mobile App was developed as a novel and attractive means of providing athletes with the “Strengthen Your Ankle” program [13]. Details of the App have been described elsewhere [3]. A recent trial (NTR 4027) showed that the App neither increased compliance nor decreased recurrence of ankle sprains compared with a standard program administered via a paper Booklet [3,4,13].

As with other preventive interventions, the translation of the evidence on ankle sprain prevention through NMT to the real-world context of sports remains a challenge, by which effective ankle sprain prevention in the community is lagging [14]. The success of introducing any intervention strategy in a practical context can be evaluated using the RE-AIM framework [15]. RE-AIM is a conceptual framework that was originally used to develop and evaluate health care programs. The goal of the RE-AIM framework is to “encourage program planners, evaluators, readers of journal articles, funders, and policy makers to pay more attention to essential program elements, including external validity, that can improve the sustainable adoption and implementation of effective, generalizable, evidence-based interventions” [16].

Although developed for use in health care settings, the RE-AIM framework has been previously used to evaluate the success of introducing strategies for sports injury prevention within a practical sports context [17,18]. Consequently, using the components of the RE-AIM framework, this study described the user experience of the “Strengthen Your Ankle” App and booklet to understand why compliance was challenged during program implementation.
METHODS

Design and Participants

The full details of the “Strengthen Your Ankle” study have been described elsewhere [3,4,13]. In brief, 220 sports participants who experienced an ankle sprain during the past 2 months were included in this RCT. Participants were randomly assigned to either the App or Booklet intervention group and were instructed to follow the embedded 8-week “Strengthen Your Ankle” NMT prevention program using either the App or the printed Booklet.

Outcome Measures

The RE-AIM framework describes five dimensions to evaluate the practical feasibility of an intervention: “Reach,” “Effectiveness,” “Adoption,” “Implementation,” and “Maintenance” [16]. The dimensions “Reach” and “Adoption” are out of scope when describing the feasibility of an intervention within a controlled trial. As such, for this study, we focused on the dimensions “Effectiveness,” “Implementation,” and “Maintenance.”

Effectiveness

The “Effectiveness” dimension describes the clinical impact of the studied intervention. The short- and long-term effectiveness of the App compared with the Booklet for preventing ankle sprain recurrences were assessed in a RCT. The full methods and results of this trial have been published elsewhere [3,4,13]. In order to put the outcomes of the “Implementation” and “Maintenance” dimensions in context, we will briefly summarize the “Effectiveness” outcomes.

Implementation

Implementation concerns the participants’ use of the intervention strategies. In this study, we quantified use as compliance with the 8-week NMT program in each of the study groups, measured as a percentage of the total program completed. In addition, the participants’ attitudes and perceptions toward the delivery of the NMT programs were assessed.

During the 8 weeks of the NMT program, participants received a weekly online questionnaire. The questionnaire registered what percentage of the program was executed during the week, the amount of difficulty that was experienced while conducting each of the exercises, and the reason for a possible lack of compliance. For each of the 6 different exercises, participants indicated what percentage of the exercises they performed each week. Additionally, using a 5-point Likert scale, participants were asked how they perceived the exercises. When participants failed to complete the questionnaire, reminders were sent by email. The details on the questionnaire have been published previously [3].

After the 8-week training period, a more extensive evaluation questionnaire was completed, including closed and free-text questions on the subjectively-experienced value
of the NMT program delivery mode, a subjective evaluation of the program, and the perceived disadvantages and advantages of the allocated intervention delivery mode. To measure satisfaction, all remaining participants (75 in the App group and 88 in the Booklet group) were asked to give a 0-10 score for the App or Booklet. An unpaired t test was performed to examine the difference in scores between the two groups.

**Maintenance**

"Maintenance" describes the long-term effectiveness of the intervention strategies. For this study, this dimension was defined as the percentage of participants still conducting the NMT program combined with the advantages the participants perceived related to the App or paper Booklet use for intervention delivery.

After 12 months, semistructured interviews were conducted with individual participants to assess the perceived advantages of using the App over the paper Booklet. All study participants were asked if they were willing to participate in a semistructured interview concerning the NMT program; 27% (32/119) of the remaining participants, evenly divided over the two study groups, responded positively. The interviews were structured using a preselected topic list on the individual experiences with the NMT program either through the Booklet or App. All interviews were conducted and transcribed by one researcher (MA). Interviews were conducted via telephone until saturation was reached, that is, when interviews did not lead to new themes or information, within both study groups, resulting in 16 semistructured interviews with 8 randomly selected participants in the Booklet group and 8 randomly selected participants in the App group. Multimedia Appendix 1 shows the question guide for the semistructured interviews, aimed at process evaluation, after finishing the 12-month intervention.

**Data Analyses**

Due to dropout during follow-up (n=57 after 8 weeks and a further n=44 after 12 months), sample sizes differed between questionnaires. The reasons for dropout were unknown. The participants’ answers on the 5-point Likert scales regarding attitudes and perceptions toward the program, as registered during the 8-week program, were averaged for each participant over the available follow-up moments. Independent sample t tests with assumed equal variances were conducted to assess for differences in the average Likert responses between the two study groups. The significance level was evaluated at P=.05. SPSS (version 22.0) and was used for all statistical analyses.

All semistructured interviews were audiorecorded and transcribed verbatim. In transcriptions, any personal information or information that was deducible to an individual was anonymized. Verbatim-transcribed interviews were thematically analyzed and fragmented on the basis of topical similarity using Atlas.ti [19]. Open, inductive coding was used line by line on the transcripts of the interviews and these codes were converged into subthemes [20]. Peer debriefing was used as an external check to the research process. This method of analysis was used after each interview and ended when no new codes arose and saturation was reached [19]. The final step in the analysis process was to submerge the subthemes to a limited number of main themes [19].
RESULTS

Effectiveness

Previous studies that looked at the effectiveness of the “Strengthen Your Ankle” program provided further details on the (cost)-effectiveness of the program in the short and long term [3,4]. In short, during the 8 weeks of the NMT, there were 93 self-reported recurrent ankle sprains, which resulted in injury incidence densities of 25.3 per 1000 hours of sport (95% CI 18.0 to 32.7) in the App group and 25.6 per 1000 hours of sport (95% CI 18.3 to 32.9) in the Booklet group. There was no significant difference in the incidence densities of self-reported recurrences (HR [hazard ratio] 3.07; 95% CI 0.62 to 15.20) [1].

During the 12-month follow-up, there were 139 recurrent ankle injuries, resulting in injury incidence densities of 15.59 per 1000 hours of sport (95% CI 11.94 to 19.24) in the App group and 15.84 (95% 12.10 to 19.58) in the Booklet group. Over the long term, this difference in injury density was not significant (HR 1.06; 0.76 to 1.49) [4].

Implementation

The first study in this larger research project looked at compliance during the 8 weeks of the NMT intervention. It was shown that the average compliance to the exercise scheme was 73.3% (95% CI 67.7% to 78.1%) in the App group and 76.7% (95% CI 71.9 to 82.3%) in the Booklet group. No significant difference in compliance was found between the groups [3].

The weekly questionnaires (Table 1) showed that participants in both the App and Booklet groups gave comparable scores with regard to simplicity, usefulness, and subjective evaluation of the exercises. Table 1 shows the averaged responses of the participants over the 8 weeks.
Table 1. Participants’ attitudes and perceptions toward the allocated delivery of the NMT program during the 8-week intervention period.

<table>
<thead>
<tr>
<th>Participants’ opinions</th>
<th>Method of delivery</th>
<th>Average (SD)</th>
<th>Mean difference$^b$ (95% CI)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>The exercises are simple.</td>
<td>App</td>
<td>3.79 (0.86)</td>
<td>0.03 (−0.19 to 0.25)</td>
<td>.79</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.76 (0.78)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Due to the variation in exercises I stay motivated.</td>
<td>App</td>
<td>2.25 (0.82)</td>
<td>−0.16 (−0.36 to 0.05)</td>
<td>.13</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.41 (0.71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I find it easy to execute the exercises without help.</td>
<td>App</td>
<td>3.72 (0.85)</td>
<td>0.05 (−0.16 to 0.26)</td>
<td>.65</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.67 (0.75)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercises give me a sense of security.</td>
<td>App</td>
<td>3.30 (0.94)</td>
<td>−0.01 (−0.25 to 0.23)</td>
<td>.96</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.30 (0.87)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercises are painful.</td>
<td>App</td>
<td>3.94 (0.68)</td>
<td>−0.04 (−0.22 to 0.14)</td>
<td>.64</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.98 (0.67)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercises don’t fit with my regular schedule.</td>
<td>App</td>
<td>3.42 (0.87)</td>
<td>0.09 (−0.14 to 0.32)</td>
<td>.47</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.33 (0.88)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have too little time to do the exercises.</td>
<td>App</td>
<td>3.29 (0.99)</td>
<td>−0.09 (−0.35 to 0.17)</td>
<td>.49</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.38 (0.97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I think the exercises take a long time.</td>
<td>App</td>
<td>2.00 (0.58)</td>
<td>−0.15 (−0.32 to −0.01)</td>
<td>.07</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.16 (0.67)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercises make me tired.</td>
<td>App</td>
<td>3.87 (0.75)</td>
<td>−0.02 (−0.21 to 0.17)</td>
<td>.84</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.89 (0.66)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I forget to execute the exercises.</td>
<td>App</td>
<td>2.34 (0.68)</td>
<td>−0.06 (−0.24 to 0.11)</td>
<td>.49</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.41 (0.64)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercises are not useful to prevent a recurrent injury.</td>
<td>App</td>
<td>3.42 (0.88)</td>
<td>0.12 (−0.11 to 0.35)</td>
<td>.32</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.31 (0.84)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The exercises won’t help me.</td>
<td>App</td>
<td>2.66 (0.77)</td>
<td>0.07 (−0.13 to 0.26)</td>
<td>.50</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.59 (0.71)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$^a$Scores present averages (SD) of 5-point Likert scales (1=strongly agree; 5=strongly disagree).

$^b$Differences in scores between groups were analyzed by independent $t$ tests with equal variances assumed.

After the 8-week intervention period, 35 participants using the App and 22 participants using the Booklet discontinued the study for unknown reasons. The remaining 75 users of the App found this method of NMT program delivery more user friendly, easier, fun to use,
and less annoying and thought that the videos were more helpful than the Booklet (Table 2). The latter question should be interpreted with caution because online videos were available for the Booklet users (n=88), but many of the participants stated that they were not aware of this possibility. Therefore, the answers of 53 of the Booklet users were “neutral” when asked if the online videos were of help; this was in comparison with 5% (4/75) in the App group. Some participants failed to answer all the questions, the number of missing responses can be found in Table 2. Additional questions specifically related to possible improvements in the App, and not the Booklet, (Multimedia Appendix 2) indicated that participants desired feedback after the exercises (44/75, 59%) and wanted the ability to postpone a training session (41/75, 55%). Overall, a t test showed that the users of the App were significantly more satisfied with the App (score 1 out of 10 with 10 referring to the highest score, mean±SD) compared with Booklet users; 7.7 (SD 0.99) versus 7.1 (SD 1.23) P=.006.

Table 2. The subjectively-experienced value of the NMT program and perceived disadvantages and advantages of the allocated intervention delivery mode assessed directly after the 8-week intervention.

<table>
<thead>
<tr>
<th>Participants’ opinions</th>
<th>Method of delivery</th>
<th>Average (SD)</th>
<th>Mean differencea (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>The intervention is user friendly.</td>
<td>App</td>
<td>1.85 (0.98)</td>
<td>-0.43 (-0.75 to -0.11)</td>
<td>.009</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.28 (1.10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The intervention is easy to use.</td>
<td>App</td>
<td>1.84 (0.92)</td>
<td>-0.40 (-0.69 to -0.11)</td>
<td>.008</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.24 (0.97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The intervention looks attractive.</td>
<td>App</td>
<td>2.12 (0.90)</td>
<td>-0.06 (-0.35 to 0.23)</td>
<td>.68</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.18 (0.97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Navigation of the intervention is clear.</td>
<td>App</td>
<td>2.13 (0.95)</td>
<td>-0.29 (-0.59 to 0.01)</td>
<td>.06</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.42 (1.01)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The intervention gives enough information.</td>
<td>App</td>
<td>2.19 (0.95)</td>
<td>-0.29 (-0.59 to 0.01)</td>
<td>.06</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.48 (0.97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I would advise others to use the intervention.</td>
<td>App</td>
<td>2.08 (1.03)</td>
<td>-0.29 (-0.62 to 0.03)</td>
<td>.07</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.38 (1.04)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It is annoying to use the intervention.</td>
<td>App</td>
<td>4.09 (1.09)</td>
<td>0.47 (0.12 to 0.81)</td>
<td>.008</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>3.63 (1.13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have used the intervention with pleasure.</td>
<td>App</td>
<td>2.25 (0.95)</td>
<td>-0.18 (-0.48 to 0.12)</td>
<td>.23</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.44 (0.97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The videos helped me (online for the Booklet).</td>
<td>App</td>
<td>1.96 (1.07)</td>
<td>-0.99 (-1.31 to -0.68)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Booklet</td>
<td>2.95 (0.96)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The written instructions helped me.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.08 (0.98)</td>
<td>−0.07 (−0.35 to 0.21)</td>
<td>.64</td>
</tr>
<tr>
<td>Booklet</td>
<td>2.15 (0.84)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The schedule helped me.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.12 (1.10)</td>
<td>0.08 (−0.23 to 0.38)</td>
<td>.62</td>
</tr>
<tr>
<td>Booklet</td>
<td>2.05 (0.87)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The intervention is boring.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3.48 (1.03)</td>
<td>−0.05 (−0.36 to 0.26)</td>
<td>.73</td>
</tr>
<tr>
<td>Booklet</td>
<td>3.53 (0.97)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The intervention makes it easier to do the exercises.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.09 (0.94)</td>
<td>−0.36 (−0.65 to −0.07)</td>
<td>.02</td>
</tr>
<tr>
<td>Booklet</td>
<td>2.45 (0.95)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The intervention makes it fun to do the exercises.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.68 (0.94)</td>
<td>−0.37 (−0.66 to −0.08)</td>
<td>.01</td>
</tr>
<tr>
<td>Booklet</td>
<td>3.06 (0.93)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The intervention is informative.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.20 (0.74)</td>
<td>−0.14 (−0.39 to 0.11)</td>
<td>.26</td>
</tr>
<tr>
<td>Booklet</td>
<td>2.34 (0.84)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The intervention is trustworthy.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.23 (0.84)</td>
<td>−0.17 (−0.42 to 0.09)</td>
<td>.13</td>
</tr>
<tr>
<td>Booklet</td>
<td>2.40 (0.870)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The explanation of the exercises is clear.

<table>
<thead>
<tr>
<th></th>
<th>App</th>
<th>Score (SD)</th>
<th>t-value (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.26 (1.07)</td>
<td>−0.22 (−0.52 to 0.10)</td>
<td>.17</td>
</tr>
<tr>
<td>Booklet</td>
<td>2.47 (0.91)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a^\)Scores present averages (SD) of 5-point Likert scales (1=strongly agree; 5=strongly disagree).

\(^b^\)Differences in scores between groups were analyzed through independent t tests with equal variances assumed.

**Maintenance**

At the end of the 12-month follow-up period, an additional 44 participants discontinued the study. These participants were asked if they were still doing (part of the) NMT program. Only 23\% (28/122) of all participants still in the study responded affirmatively. We did not ask what amount of the program they were still doing.

Two main themes arose from the semistructured interviews that related to the design of the App and possible additional benefits of the App. Fourteen out of 16 participants stated that an App would provide an additional benefit compared with a Booklet. The main reasons given were that most of the participants always had their mobile phones with them and that the App provided visual support and had a reminder function. The two participants who did not feel that the App offered any benefit found the exercises too easy, which made the App redundant.

Errors in navigation and explanation, the lack of feedback and music, and lack of explanation of the purpose of the exercises were the main disadvantages experienced by the App users. The greatest perceived disadvantages of the Booklet were the big size when folded out, small font, lack of robustness, and errors in explanation. Table 3 shows the individual responses during the semistructured interviews to illustrate the flavor of the original data and demonstrate the prevalence of the themes, as suggested by King [21].
Table 3. Individual responses from semistructured interviews.

<table>
<thead>
<tr>
<th>Respondent</th>
<th>Added benefit of the app?</th>
<th>Reason given</th>
<th>Pros (+) and suggestions for improvement (−) for the app</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>App</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R1</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>+ Easy to use + Agenda function + Videos with instructions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>You forget the booklet</td>
<td></td>
</tr>
<tr>
<td>R2</td>
<td>No</td>
<td>The exercises are so easy, you don’t need an app</td>
<td>+ Videos with instructions + Tick off done exercises</td>
</tr>
<tr>
<td>R3</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>+ Tick off done exercises – Show why you need to do an exercise</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Seeing the app on my phone reminds you to do the exercises</td>
<td></td>
</tr>
<tr>
<td>R4</td>
<td>Yes</td>
<td>The app gives visual support</td>
<td>+ Easy to use + Videos with instructions</td>
</tr>
<tr>
<td>R5</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>+ Easy to use</td>
</tr>
<tr>
<td>R6</td>
<td>Yes</td>
<td>The app is smaller and thus easier to use</td>
<td>+ Easier navigation</td>
</tr>
<tr>
<td>R7</td>
<td>Yes</td>
<td>The app gives visual support</td>
<td>+ Videos with instructions + Counting down the number of exercises</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Seeing the app on my phone motivates you to do the exercises</td>
<td></td>
</tr>
<tr>
<td>R8</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>+ Videos with instructions + Tick off done exercises</td>
</tr>
<tr>
<td><strong>Booklet</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R9</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>– Show why you need to do an exercise. + Reminder to do the exercises.</td>
</tr>
<tr>
<td>R10</td>
<td>No</td>
<td>The exercises are so easy, you don’t need an app</td>
<td>– Stopwatch function</td>
</tr>
<tr>
<td>R11</td>
<td>Yes</td>
<td>The app gives visual support</td>
<td>– Show why you need to do an exercise</td>
</tr>
<tr>
<td>R12</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>+ Reminder to do the exercise – Possibility to postpone exercises</td>
</tr>
<tr>
<td>R13</td>
<td>Yes</td>
<td>The app gives visual support</td>
<td>+ Videos with instructions</td>
</tr>
<tr>
<td>R14</td>
<td>Yes</td>
<td>You always have your phone with you</td>
<td>– Direct translation of the app to a booklet</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Seeing the app on my phone would remind you to do the exercises</td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

**Principal Findings**

Previous studies [3,4] have shown that using an App or a Booklet with a special NMT program to prevent recurrent ankle sprains has resulted in comparable injury densities during both short- (8 weeks) and long-term (12 months) follow-ups and comparable compliance rates with the program. During the execution of the program during the first 8 weeks, the App and Booklet were given comparable scores for simplicity, usefulness, and liking of the exercises. After the 12-month follow-up, the users of the App were significantly more satisfied with the App compared with the users of the Booklet. The users of the App evaluated the App as more patient friendly, easier to use, and less annoying and thought that the videos were helpful. With the help of semistructured interviews, 14 out of 16 participants agreed that an App would be of additional benefit over a Booklet, mainly due to use of instructional videos, phone portability, and the agenda function. Further suggestions for improving the App that were mentioned by various participants were the ability to postpone exercises and the provision of exercise feedback.

Interventions for preventing sport injuries require high participant compliance [3]. Therefore, ways to increase compliance are a focus of many intervention studies [3]. The “Strengthen Your Ankle” program was developed in 2009. Since then, the program has been studied intensively [3,4,9-11,22]. It was shown that (1) the program was effective in reducing recurrent ankle sprains for those with high compliance [10], (2) the use of either the App or a Booklet produced nonsignificant differences in injury densities in both the short and long term [3,4], and (3) both methods had comparable cost-effectiveness of implementation [23].

Over the years, compliance with the “Strengthen Your Ankle” program in RCTs has steadily increased from 23% [9] to 45% [10] and 75% [3], likely as a result of annual updates, increased acknowledgment of the usefulness of the program by the target population, and improvements in the program content. However, the reach of the target population still requires substantial attention. In 2011, the annual number of downloads of the “Strengthen Your Ankle” App reached 25,781, which corresponds to a low percentage (25,781/911,576, 2.6%) of potential users [18]. Some studies have looked at the use of Apps in injury prevention over the last decade. What can be concluded from those studies is that numerous Apps seek to prevent (re)injury. However, the scientific evidence supporting these App-based programs is nonexistent or scarce [22,24]. A recent review found that out of 18 apps concerned with preventing sports and physical activity-related injuries, only four included evidence regarding efficacy [22]. In addition to the App that is the focus of this study, one of those four apps dealt with ankle injury prevention using NMT. No information is available on the use or compliance of the other App [22].

This study aimed to explore user experiences with the NMT program, as well as with the App and Booklet as delivery methods, by means of semistructured interviews. The
information gathered can be used to further improve the methods of delivery and, thus, increase future reach and compliance. The interviews and questionnaires showed that the App and Booklet can be successfully used to prevent recurrent ankle sprains and that both show high user satisfaction. Future updates may include options for feedback or postponement of exercises, an explanation of the use of specific exercises, and possibly music; these additions could further improve user perceptions of the program and hence increase compliance.

A limitation of this study, and that of previous studies on the “Strengthen Your Ankle” program, is the mismatch between compliance and adherence. Although both constructs have been used interchangeably, they are not synonymous. Adherence refers to a situation where a clinician or researcher develops a program in cooperation with the participant. The participant attempts to follow the program as best as possible, taking personal preferences and constraints into consideration. Adherence can be seen as what happens in real-life conditions when individuals with an ankle sprain try to follow the program; compliance is studied in clinical settings. The extent to which the participant obeys the program instructions is measured by compliance rates [12,24]. Research, ideally performed in a more or less controlled setting, implicitly focuses on compliance, rather than on adherence. However, the “Strengthen Your Ankle” program is meant to increase adherence for all individuals at risk for an ankle sprain, not only for those who participate in the studies involved. This study has tried to explore the barriers and opportunities that participants experienced while using the training program via an App or Booklet within a controlled study setting. However, because the interviews were held after follow-up, that is, months after the participants had finished the 8 weeks of the training program, we expected to gain insight as to program performance in real-life situations.

A further limitation of this study is the possibility of selection bias for the semistructured interviews. It is possible that only those participants that carried a strong negative or positive view of the program agreed to participate because the invitation for the interviews was made only after termination of the 12-month follow-up. Additionally, the (single) interviewer did not structure the interviews and continued to question the participants when needed. This may have affected the validity of the data analyses. However, it is recognized that this characteristic is inherent to the flexible nature of thematic analysis and does not threaten the depth of analysis [5].

Conclusions

With the use of semistructured interviews and online questionnaires, we were able to evaluate users’ opinions on both the App and Booklet. The users of the App were significantly more satisfied with the App although there was no significant difference in the perceived simplicity, usefulness, and liking of the exercise during the 8 weeks of the NMT program. In the interviews, users acknowledged the need for improvements. Future updates should take the users’ suggestions into account because adherence with the NMT program remains an ongoing challenge.

ACKNOWLEDGEMENTS

This study was funded by the Netherlands Organisation for Health Research and Development (ZonMw) grant number 525001003, Balance boards were provided by Disporta and Booklets were provided by VeiligheidNL.
We would like to thank the following partners for their collaboration and recruitment of study participants: Royal Dutch Society for Physical Therapy (KNGF), Dutch Society for Physical Therapy in Sports (NVFS), Dutch College of General Practitioners (NHG), Dutch Sports Medicine Society (VSG), Dutch Olympic Committee (NOC*NSF), Zilveren Kruis Achmea (ZKA), and Disporta.

Conflicts of Interest
None declared.

Abbreviations

ESSM: exercise science and sports medicine
HR: hazard ratio
NMT: neuromuscular training
RCT: randomized controlled trial
ZKA: Zilveren Kruis Achmea
REFERENCES


Multimedia Appendix 1: Question guide for the process evaluation using semi-structured interviews after finishing the 12 months’ intervention period.

### Question guide for the App

It is true that you have used the App to follow the Strengthen your ankle training program?
Did you execute the 8 weeks of the training program as instructed?
If no, what was the reason for not following the training program as instructed?
How much of the training program did you follow?
Do you still follow the training program now?
Can you elaborate on how you have experienced:
- The usability
- The provided information
- The design
How did the app contribute to the Strengthen your ankle program?
If the App would be updated, what would you like to improve?
Currently there are many medical applications available. Would you only use these apps when a medical professional advice you to do so?
Would you advice others to use the App to follow the Strengthen your ankle training program?
Are there any remarks you want to make concerning the App or the program?

### Question guide for the Booklet

It is true that you have used the booklet to follow the Strengthen your ankle training program?
Did you execute the 8 weeks of the training program as instructed?
If no, what was the reason for not following the training program as instructed?
How much of the training program did you follow?
Do you still follow the training program now?
Can you elaborate on how you have experienced:
- The usability
- The provided information
- The design
You might be aware of the fact that there is also a mobile App available with the Strengthen your ankle program. Do you think the app would contribute to the training program?
And if yes, how?
How would you like a mobile application to be developed? What features would you prefer?
Currently there are many medical applications available. Would you only use these apps when a medical professional advice you to do so?
Would you advice others to use the Strengthen your ankle training program?
Are there any remarks you want to make concerning the possibility of an App or the program?
**Multimedia Appendix 2: Responses to process evaluation of the neuromuscular training program after the intervention period**

<table>
<thead>
<tr>
<th>What are the three greatest benefits of the App?</th>
<th>What are the three greatest disadvantages of the App?</th>
<th>Verbatim examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visual aspects</strong></td>
<td><strong>Errors in navigation</strong></td>
<td>“The video’s help me to do the exercises because they show me how I should do them.”</td>
</tr>
<tr>
<td>Video’s and sounds</td>
<td>Need to have phone at hand</td>
<td></td>
</tr>
<tr>
<td>Easy to navigate</td>
<td>No possibility to postpone</td>
<td></td>
</tr>
<tr>
<td>Looks good</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Informational aspects</strong></td>
<td><strong>Errors in explanation</strong></td>
<td>“The app helped me with information on the exercises.”</td>
</tr>
<tr>
<td>Schedule</td>
<td>Lack of explanation of purpose of exercise</td>
<td></td>
</tr>
<tr>
<td>Information on brace/tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Written information</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Motivational aspects</strong></td>
<td><strong>Lack of feedback</strong></td>
<td>“I would love to get feedback on why I should do a particular exercise and what exactly I’m training.”</td>
</tr>
<tr>
<td>The reminder function</td>
<td>No timer function</td>
<td></td>
</tr>
<tr>
<td>Telephone is always at hand</td>
<td>No music</td>
<td></td>
</tr>
<tr>
<td>Less boring to do the exercises</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What are the three greatest benefits of the Booklet</th>
<th>What are the three greatest disadvantages of the Booklet?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visual aspects</strong></td>
<td><strong>No possibility to turn pages</strong></td>
</tr>
<tr>
<td>Compact</td>
<td>Big when folded out</td>
</tr>
<tr>
<td>Looks good</td>
<td>Small letters</td>
</tr>
<tr>
<td>Strong material</td>
<td>Lack of video’s</td>
</tr>
<tr>
<td></td>
<td>Not robust</td>
</tr>
<tr>
<td></td>
<td>Not easy to unfold</td>
</tr>
<tr>
<td><strong>Informational aspects</strong></td>
<td><strong>Too short in information</strong></td>
</tr>
<tr>
<td>Schedule</td>
<td>Difficult schedule</td>
</tr>
<tr>
<td>Figures</td>
<td>Errors in explanation</td>
</tr>
<tr>
<td>To the point</td>
<td></td>
</tr>
<tr>
<td>Information on brace/tape</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Motivational aspects</strong></td>
<td><strong>Lack of feedback</strong></td>
</tr>
<tr>
<td>Easy to carry</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER 8
General discussion

eight.
The aim of this thesis was to evaluate the value of the 'Versterk je Enkel' App as compared to the usual practice of providing injured athletes with advisory printed materials. The premise was that use of the 'Versterk je Enkel' App would increase compliance to the prescribed evidence-based preventive program and, consequently, would decrease ankle sprain recurrence incidence. The findings from this study ultimately advance the development of a practical evidence-based guideline on 'how to effectively reduce the risk of ankle sprain recurrences'. Ideally, this guideline should deal with two issues. First, the guideline should be evidence-based and feasible in a real-life situation. Second, the intervention should be cost-effective for society and should be implementable at a large scale. In order to develop such a guideline, this thesis addressed and answered the following questions.

**How does compliance affect study results in sports injury studies?**

Studies that have been done previously on the 'Versterk je Enkel' neuromuscular training program provided us with clear future recommendations. It was shown that the program had the potential to significantly reduce the risk of recurrent ankle sprains. However, ensuring compliance with the program turned out to be a considerate and continuing challenge. In order to find out how compliance is dealt with in sports injury prevention studies this thesis, therefore, describes in **chapter 3** a systematic review on the use and recognition of compliance and adherence in sport injury prevention trials. It was clearly demonstrated that assuming that the entire study population had complied with the prescribed intervention could lead to erroneous conclusions. To further complicate matters, many different definitions of compliance have been reported in the sports medicine literature [1]. Also, although compliance and adherence are not synonymous [2,3], these constructs are being used interchangeably to describe the complete and correct following of a prescribed intervention. Compliance refers to participant obedience in a study where a clinician or researcher prescribes the intervention, with little to no right of consultation on behalf of the participant; compliance can thus be defined as “the athletes’ correct and complete following of a prescribed intervention” [2]. Adherence implies a collaborative environment in which a clinician or researcher and a study participant work together to develop an intervention that aligns with the participants’ opportunities and barriers [4,5]. Research, ideally performed in a more or less controlled setting such as the current study, therefore implicitly focuses on compliance, rather than on adherence. In this review it was further concluded that injury prevention studies vary significantly in the way they define, measure and adjust for compliance. While the majority of included studies do mention the concept of compliance, only one-fifth of the studies gave a more detailed account of how compliance rates influenced their study results. The studies that did account for compliance demonstrated that the level of compliance could have a significant effect on study outcomes. Acknowledging the importance of compliance, we ensured to clearly define, measure and report this concept and showed how compliance affected outcome measures.
Does the use of an App increase compliance to the program?

In the short-term effectiveness study (chapter 4) this thesis examined whether the use of the mobile ‘Versterk je Enkel’ App increased compliance to the intervention program, in comparison to a printed Booklet. Participants were asked weekly about their compliance with the ‘Versterk je Enkel’ program and about the recurrence of self-reported ankle injury. This thesis shows that the method of implementing the ‘Versterk je Enkel’ program, i.e. using an App versus a Booklet, did not lead to significant different mean overall compliance rates. Additionally, the percentage of participants that was highly compliant – i.e. those following at least 70% of the program, the arbitrary threshold necessary for the program to be efficacious - was not different between groups. In both groups, 74.5% of participants complied with the neuromuscular training programme during the 8 weeks in which they participated in the study. The short-term study thus showed that compliance was not influenced by the implementation method.

Better effectiveness of the NMT program when delivered by App?

Chapter 5 described the results after completion of the NMT program, at 10 months follow-up. Participants were asked to complete an online questionnaire at the end of each month to register any recurrent ankle sprain and residual functional disability or pain. In this study it was shown that the implementation method of the NMT program by either an App or a Booklet did neither lead to different injury incidence rates at 10 months follow-up, nor to differences in residual functional disability or pain. From the above findings one can conclude that when the participant is compliant with the program, both methods showed similar effectiveness in reducing the risk of recurrent ankle sprains, on both the short and the long term.

Is the NMT program more cost-effective when delivered through an App?

Considering that both the App and the Booklet resulted in similar short and long-term effectiveness and compliance, the thesis’ next question dealt with cost-effectiveness. The cost-effectiveness study in chapter 6 this thesis addressed two questions. Firstly, is there a difference in direct and indirect costs during a 10-month follow-up, between groups applying the ‘Versterk je Enkel’ App and written materials? And secondly, is there a difference in ankle sprain residual complaints (i.e. instability, feeling of giving way, pain, and continued sports participation) after a 12-month follow-up, between groups applying the ‘Versterk je Enkel’ App and written materials? Primary outcome measures of the analyses were the incidence density of ankle injury and the incremental cost-effectiveness ratio (ICER). It was shown that over the 10-month of follow-up, there was neither a difference in effects, nor in costs between both intervention methods. This study showed, as such, that the method of implementing the NMT program using an App or a Booklet can be used to prevent recurrent ankle injuries, showing no differences in (cost-) effectiveness at 12-month follow-up.
What are the barriers and facilitators that affected program and how can the 'Versterk je Enkel' program be improved?

From the five studies presented in this thesis one could conclude that in terms of effectiveness, the effect on compliance, and the cost-effectiveness, both the App and the Booklet can be used to reduce the risk of recurrent ankle injury. This thesis’ final inquiry was to find out how participants evaluated the use of both methods of delivery. In Chapter 7 this thesis presented a qualitative evaluation of the neuromuscular training program based on semi-structured interviews and open questionnaires. Multiple, individual barriers and facilitators of the final users were identified via a process evaluation. The RE-AIM framework was used to get insight in the adoption and implementation of the program. This framework is seen as a ‘reporting template’ to encourage sports researchers to document their research in way that enables practitioners, policy makers and communities to use them effectively’ [6]. The study described in chapter 7 employed in-depth interviews to analyse participants’ valuation of the NMT program while either using an App or a printed Booklet. The study looked at their challenges to comply with the NMT program and questioned their opinion on possible improvements for the intervention and mode of delivery. There was no difference in perceived simplicity, usefulness and liking of the exercise between the program delivered through the App or the Booklet. After twelve months’ follow-up, users of the App were significantly more satisfied with the App than users of the Booklet with the Booklet: 7.7±0.99 versus 7.1±1.23 (P = .005). Participants provided us also with ideas on how the App could be improved to live up to their expectations and how these improvements could help them to increase their compliance with the program. The instructional videos, the agenda function and the simplicity of the App were functions that were highly appreciated. As examples of further improvements, a function to postpone a training session was mentioned, as well as functions to provide music and feedback on exercises executed.

METHODOLOGICAL CONSIDERATIONS

Each of the chapters present methodical considerations that are unique for the individual questions addressed. Nonetheless, some considerations are underlying the nature of sports injury research and are presented below.

One of the most important limitations of our study was the regular contact with the participants. Our study involved 220 athletes from different levels and different sports. During follow-up we regularly contacted the participants via email, and in case of non-response by phone. This initial weekly (first 8 weeks) and later monthly contact most likely affected the study results. Although it is unknown how compliance was influenced by participation in this study, one could argue that the regular contact increased compliance with the program, as compared to a real-life situation where the participants are not required to report how much of the program they executed. In other words, contacting the participants may have compromised external validity. As our method provided the only possibility to measure compliance with the program we did decide to do so.

A further limitation of the study was the high rate of drop-out during the study process. During the first 12 months of follow-up, 35 participants (15.9%) dropped-out. Their reasons for drop-out were lack of time or motivation to continue the program, or lack of
time or motivation to continue the study (and replying to the weekly and monthly questionnaires). It is not known if the participants who had dropped-out did or did not find that they had benefitted from the program and had or had not endured re-injury. Therefore, it is unknown if complete absence of drop-out would have led to a decrease or increase of the number of injuries. The high number of drop-outs, does show again that, although participants were regularly contacted, motivation to comply with the program remains a complex issue.

Unique for this study is the accurate calculation of compliance rates in the first 8 weeks of the intervention. The online weekly questionnaires allowed us to determine what part of the program was completed by the participants and which exercises where executed or not. This allowed for a robust evaluation of compliance rates for the entire duration of the 8-week intervention program. Furthermore, the semi-structured interviews provided us with detailed analyses of the participants’ evaluation of the program after they had experienced the use of it. This implies that we can, and should, not only include those involved in developing an intervention, but also using the findings for future updates.

A further strength of the current study was the collaboration of important stakeholders right from the onset of this project. By doing so the project aimed to reduce the time lag from introducing findings from research to changing guidelines, policies and practices [7]. With every step of the process, national sport federations, the National Olympic Committee, Dutch health care insurance companies and federations for general practitioners and physiotherapists were involved and enthusiastic to discuss our advice and findings. Additionally, this allowed us to relate our scientific methods and findings to a real-life setting. After finalisation of this project, this collaboration will allow for the realisation of an updated guideline for the prevention of recurrent ankle sprains. Via our stakeholders, who are involved in the writing of this guideline, our knowledge can be transferred to those who may benefit from the program.

**FUTURE DIRECTIONS**

*What can be improved in future research?*

*Involving stakeholders*

To further develop and improve the implementation of the ‘Versterk je Enkel’ program it is important that the end-users are involved from a very early start of program development and that athletes and stakeholders identify each other’s possibilities and barriers. Assuming that the results from controlled trials can be easily translated to a real-life situation would neglect the influence of the multiple determinants that influence the athletes’ behaviours involved [6], often in a non-linear fashion. As astutely advised by Hanson [6] it is important not only to ensure correct translation from research evidence into practice, but also to allow for a “better translation of evidence from practice into research”, such that future research is based on a multidirectional conversation involving scientists, stakeholders and athletes. And although there might be a need for the continued existence of traditional paper-based forms of intervention materials, digital tools can be used not only to deliver the specific program, but also to collect data from the athlete that can be used to further improve the intervention program [8], such that all participants are part of each development phase of an intervention.
Dealing with compliance

From our review study it became clear that valid and reliable tools to measure and report compliance are needed and should be matched to a uniform definition of compliance. A number of study-reporting guidelines, such as the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement and the CONSORT (CONsolidated Standards Of Reporting Trials) statement, recognise the importance of compliance and include specific items on the topic in their guideline [9, 10, 11]. The CONSORT statement specifically addresses the quality of reports of randomised controlled trials (RCTs). Until 2010, the CONSORT statement advocated the use of ITT analysis for RCTs. ITT analysis does not include the measurement of compliance but assumes non-adherence to the prescribed intervention [2]. However, as mentioned in the CONSORT statement, strict ITT analysis is often hard to achieve for two main reasons: missing outcomes for some participants and non-adherence to the protocol. Therefore, since 2010, the CONSORT statement has replaced the mention of ITT by the requirement of “more information on retaining participants in their original assigned groups” [9]. As an alternative to an ITT analysis, it has been suggested that per-protocol-analysis (PPA)—sometimes referred to as ‘modified ITT’—can be used [2]. In this approach, the analysis is performed only on those participants who have fully complied with the programme. A PPA can provide a measure of efficacy in that it gives the result of a prescribed programme that is implemented exactly as the researcher originally developed it, assuming that non-compliance is not due to the intervention itself. The CONSORT statement argues that, in order to evaluate both efficacy (with the assumption of full compliance and no recognition of implementation barriers) and effectiveness (the real-life adoption of an intervention), researchers should analyse study results using ITT, PPA and a graded compliance measure [9]. The latter refers to the extent to which participants have complied with the programme and what effect this has had on the outcome.

What are the implications for practice?

While examining the progress of the 'Versterk je Enkel' program over the last decade, it is clear that the program and its implementation have evolved. In the first studies, compliance with the program was considerably lower than in the current study. In the first study that examined the effectiveness of the same NMT programme using written materials only, rates of participants who showed high compliance were as low as 23% [12]. Four years later, in a comparable study full compliance with the program increased to 45% [13]. In the current study, the percentage of participants that was highly compliant was 65%. It was argued that with time the neuromuscular training programme had become more widely accepted in the Netherlands. This might explain the increase in compliance rates. With a further increase in the number of downloads and campaigns to support the 'Versterk je Enkel' program it is possible that the neuromuscular training programme will show increased acceptance in practice even further. In addition, the previous studies used a printed paper version, with a simple layout. Both the Booklet and the App used in the current study were updates of the materials that have been used in the previous studies. We hypothesize that the Booklet and the App used in our study may have had a more attractive format, which resulted in increased compliance rates. However, although compliance in the current study showed a significant increase compared to previous studies on the same program, to effectively
reduce the persistent existence of sports injuries, we should continue to look for interventions with the lowest barriers to use. Our process evaluation provided us with clear instructions on how to further improve both methods of implementation such that they live up to users’ expectations and further enhance compliance with the program. It is important that future updates take these recommendations into account. With the collaboration of the stakeholders involved in this research process we hope to have a decisive impact on the future guidelines.

*Allow co-existence of innovative and traditional methods*

In the past decennia a vast number of mobile apps have entered the sport injury prevention arena. The increased use of mobile phones in all areas of modern life might have led to the assumption that apps can, and should, be exclusively used as effective methods to deliver injury prevention interventions to those involved. However, with the use of the in-depth interviews, the help of the stakeholders and our thorough analysis of compliance and (cost-)effectiveness we learned from this study that there is no such thing as THE (injured) athlete with set determinants of behaviour. Each of the 220 participants had its own story on how the first ankle sprain arose, if and how it was treated and how the individual went about preventing (or not) re-injury. During both the short and the long term, each of the participants had to find the time, the motivation and the resources to do so. Some succeeded, some did not and some only to a certain extent. It became clear that not all participants preferred the use of the mobile app. This led us to conclude that traditional methods of delivery should not be forgotten and if possible, should co-exist with more innovative, mobile options. With multiple options, the diversity in individual limitations and barriers can be acknowledged. Or, as clearly stated by Green and cited by others: “Where did the (sport injury research) field get the idea that evidence of an intervention’s efficacy from carefully controlled trials could be generalized as ‘best practice’ for widely varied populations and situations” [6, 14, 15]?

**OVERALL CONCLUSIONS**

We found that the method of implementing did neither lead to different rates of compliance nor to differences in (cost-)effectiveness. Both in the short and long term, rates of re-current ankle sprain were similar when using the App or the Booklet, and compliance with the program did not differ between both methods during the 8 weeks of the intervention. Our advice for the individual athlete and the stakeholders involved would therefore be to use the method that is preferred by the athlete. This can be the App, the Booklet or even a combination of both, such that the athlete can choose the method of implementation that is most easily accessible at a certain moment of time. Our main message is that the program *is* effective but *should* be executed.
REFERENCES


SUMMARY

While exercise is generally advocated to contribute to overall well-being, it comes with a health risk, both for the individual, as for society as a whole. The body parts that are most often affected by an injury are the knee and the ankle, with respectively 970,000 and 680,000 injuries in the Netherlands alone. The single most common injury is an ankle sprain, which makes up 85% of all ankle injuries. In addition to societal costs, there is extensive evidence that there is an up to twofold increased risk for ankle re-injury during the first-year post-injury. In about 50% of all cases recurrences may result in disability, can lead to chronic pain or instability and may require prolonged medical care. As such, ankle sprains pose a significant burden to the individual athlete and to society.

Previous research has shown that both externally applied ankle supports (i.e. taping or bracing), as well as neuromuscular training programs are successful in preventing recurrent cases of ankle sprain, both from an effectiveness, as well as a cost-effectiveness perspective. These measures can reduce the increased risk of recurrent injury to the same level as never injured athletes. However, although the neuromuscular program has been proven (cost-)effective compliance with the program is poor.

The aim of this thesis is to evaluate the implementation value of the ‘Versterk je Enkel’ App as compared to the usual practice of providing injured athletes with ‘ordinary’ materials. The premise is that use of the ‘Versterk je Enkel’ App would increase compliance to the prescribed program and, consequently, would decrease ankle sprain recurrence incidence.

Chapter 2 – The foundation for all included publications in this thesis

Chapter 2 describes the study design of the ‘Verstek je Enkel’ research line that is the foundation for this thesis. It explains in detail how the participants have been recruited and how the flow of athlete recruitment was executed. Chapter 2 also provides details on the ‘Versterk je Enkel’ program with visual examples of the included exercises and graded schedule.

Chapter 3- Delving into the concept of compliance

An important part of this thesis deals with the concept of compliance. Chapter 3 shows the results of extended review on sport injury intervention studies. It shows how compliance is defined, measured and dealt with in 100 RCT’s. It was shown that assuming an entire study population complies with the prescribed intervention could lead to erroneous conclusions. To further complicate matters, many different definitions of compliance are used and although compliance and adherence are not synonymous, these constructs are being used interchangeably to describe the complete and correct following of a prescribed intervention. While the majority of included studies in the review, do mention the concept of compliance, only one-fifth of the studies gave a more detailed account of how compliance rates influenced their study results. The studies that did account for compliance demonstrated that the level of compliance could have a significant effect on study outcomes.
Chapter 4 - Short term results from the 'Versterk je Enkel' programme

Chapter 4 presents the results from the short-term study. It compared the compliance rates of the intervention program from App users with those using a printed Booklet. Participants were asked weekly about their compliance with the 'Versterk je Enkel' program and about the recurrence of self-reported ankle injury. It was shown that using an App versus a Booklet, did not lead to significant different mean overall compliance rates. Additionally, the percentage of participants that was highly compliant – i.e. those following at least 70% of the program, the arbitrary threshold necessary for the program to be efficacious - was not different between groups. The mean compliance to the exercise scheme was 73.3% (95% CI: 67.7-78.1) in the App group, compared to 76.7% (95% CI: 71.9-82.3) in the Booklet group. Additionally, the incidence densities of self-reported time-loss recurrences were not significantly different between both groups (HR 3.07; 95% CI 0.62-15.20).

Chapter 5 - Long term effectiveness - a 12-month follow-up

After the intervention program that lasted for 8 weeks, participants were followed-up for another 10 months. They were asked to complete online questionnaire monthly to examine re-injury and to register any residual functional disability or pain. After the total time frame of 12 months, there were no differences in injury incidence rates (HR 1.06; 95% CI 0.76-1.49) nor differences in residual functional disability or pain. It was concluded that when the participant is compliant with the program, both methods showed similar effectiveness in reducing the risk of recurrent ankle sprains, on both the short and the long term.

Chapter 6 – Which program is more cost-effective?

Primary outcome measures of Chapter 6 were the incidence density of ankle injury and the incremental cost-effectiveness ratio (ICER) during 12 months follow-up. During follow-up 31 athletes suffered from a recurrent ankle sprain that led to costs resulting in a Hazard Ratio of 1.13 (95% CI: 0.56-2.27). The incremental cost-effectiveness ratio (ICER) of the App group in comparison with the Booklet group was €361.52. The CE plane presented in chapter 6 shows that there was neither a difference in effects nor in costs between both intervention methods.

Chapter 7 - A thorough examination of user experiences

To evaluate the ‘Versterk je Enkel’ NMT program we used the RE-AIM framework as a reporting template. We looked at the implementation and maintenance phase to identify the barriers and facilitators as experienced by the final users. Semi-structured and online questionnaires showed that there was no significant difference in perceived simplicity, usefulness and liking of the exercise during the eight weeks of the NMT program. 14/16 participants from the interviews agreed that an App would be of additional benefit over a Booklet. After twelve months’ follow-up, when asked how they evaluated the overall use of the App or the Booklet, users of the App gave a mean score of (mean ± sd) 7.7±0.99 versus
a mean score of 7.1±1.23 for the users of the Booklet. This difference in mean score was significant (p=0.006).

CONCLUSION

We found that the method of implementing the ‘Versterk je Enkel’ NMT program did neither lead to different rates of compliance nor to differences in (cost-)effectiveness. Both in the short and long term, rates of re-current ankle sprain were similar when using the App or the Booklet, and compliance with the program did not differ between both methods during the 8 weeks of the intervention. The semi-structured interviews and our thorough analysis of compliance and (cost-)effectiveness showed us that there is no such thing as THE (injured) athlete with set determinants of behaviour. Each of the 220 participants had its own story on how the first ankle sprain arose, if and how it was treated and how the individual went about preventing (or not) re-injury. During both the short and the long term, each of the participants had to find the time, the motivation and the resources to do so. Some succeeded, some did not and some only to a certain extent. It became clear that not all participants preferred the use of the mobile app. This led us to conclude that traditional methods of delivery should not be forgotten and if possible, should co-exist with more innovative, - mobile - options. With multiple options, the diversity in individual limitations and barriers can be acknowledged. Our advice for the individual athlete and stakeholders involved would therefore be to use the method that is preferred by the athlete. This can be the App, the Booklet or even a combination of both, such that the athlete can choose the method of implementation that is most easily accessible at a certain moment of time. Our main message is that the program is effective but should be executed.
SAMENVATTING

Hoewel beweging en sport bij kan dragen aan een goede gezondheid brengt het ook het risico van blessures met zich mee. Blessures kunnen leiden tot aanzienlijke kosten voor zowel het individu als voor de gemeenschap als geheel. De lichaamsdelen die het vaakst geblesseerd raken zijn de knie en de enkel met jaarlijks respectievelijk 970.000 en 680.000 blessures in Nederland. 85% van de blessures betreft een verstuiking van de enkel. Het is hiermee de meest voorkomende blessure. Naast de maatschappelijke kosten van deze blessures, brengt een eenmalige enkelverstuiking ook een tweevoudig risico op herletsel met zich mee voor de getroffene in het eerste jaar na het letsels. In ongeveer 50% van de gevallen leidt herietsel tot chronische pijn, instabiliteit of van langdurige invaliditeit. Het moge duidelijk zijn dat enkelletsel voor zowel de maatschappij als het individu grote problemen met zich mee kan brengen.

Eerder heeft onderzoek aangetoond dat hulpmiddelen (zoals tape of een brace) en een neuromusculair trainingsprogramma (het Versterk je Enkel oefenprogramma) succesvol zijn in het voorkomen van herletsel. Dit betreft zowel het aantal herletsel als de kosteneffectiviteit van deze interventies. Personen die deze hulpmiddelen gebruiken kunnen hun risico op herletsel reduceren tot hetzelfde level als personen die nooit geblesseerd zijn geweest. Het probleem is echter dat de therapietrouw van deze interventies zeer laag is.

Het doel van deze thesis is om de implementatie van de ‘Verstek je Enkel’ App te vergelijken met hetzelfde programma maar dan in de vorm van een geprint boekje. De uitkomsten van de thesis kunnen zo een bijdragen leveren aan de huidige richtlijnen voor het verminderen van recidief enkelletsel.

**Hoofdstuk 2 – Het fundament van het onderzoek**

Hoofdstuk 2 is het gepubliceerde onderzoeksontwerp zoals gepresenteerd aan het begin van deze onderzoekslijn. Het bevat een gedetailleerde (visuele) uitleg van het programma en de manier waarop de deelnemers zijn gerekruiteerd. We maakten bij het werven van de deelnemers uitvoerig gebruik van de kanalen van onze consortiumpartners.

**Hoofdstuk 3 – Therapietrouw nader bekeken**

Een belangrijk deel van deze thesis gaat over het concept therapietrouw (compliance). Hoofdstuk 3 laat de resultaten zien van een review naar therapietrouw in interventiestudies met betrekking tot sportblessurepreventie. Het hoofdstuk laat zien hoe dit concept in meer dan 100 RCT’s wordt gedefinieerd, berekend en geanalyseerd. In de review kwam naar voren dat de aannames dat alle deelnemers volledig therapietrouw zijn, kan leiden tot onjuiste conclusies aangaande de effectiviteit van de interventie. In de onderzochte studies worden bovendien tal van verschillende definities voor het concept gehanteerd en wordt het concept ‘adherence’ veelal onjuist gebruikt als synoniem voor therapietrouw (compliance). Hoewel het merendeel van de studies wel aandacht besteedt aan het concept, geeft slechts een vijfde deel aan hoe ze therapietrouw berekenen en hoe dit invloed heeft op de studieresultaten. De studies die wel nadrukkelijk kijken naar therapietrouw laten zien dat het concept grote invloed heeft op de uiteindelijke conclusies.
Hoofdstuk 4 – De effectiviteit van het oefenprogramma op de korte termijn

Hoofdstuk 4 laat de resultaten zien van de studie naar de acht weken waarin de deelnemers het ‘Versterk je Enkel’ oefenprogramma volgen. In dit hoofdstuk tonen we het verschil in therapietrouw en zelf-gerapporteerde, recidief enkelletsel gedurende deze periode. De deelnemers werd gevraagd wekelijks een online vragenlijst in te vullen. We lieten zien dat er geen significant verschil bestaat tussen therapietrouw wanneer het boekje wordt gebruikt in vergelijking met de mobiele App. Ook het verschil in deelnemers dat ten minste 70% van het programma uitvoerden - de arbitraire drempel die nodig is om het programma effectief te laten zijn – was niet verschillend tussen beide groepen. De gemiddelde therapietrouw was 73.3% (95% CI: 67.7-78.1) in de Appgroep, vergeleken met 76.7% (95% CI: 71.9-82.3) in de groep die het boekje gebruikte. Tenslotte bleek ook het voorkomen van recidief enkelletsel dat leidde tot tijdverlies niet verschillend (HR 3.07; 95% CI 0.62-15.20).

Hoofdstuk 5 - De effectiviteit van het oefenprogramma op de lange termijn

Na het ‘Versterk je Enkel’ oefenprogramma werden de deelnemers nog 10 maanden gevolgd. In deze periode werd hen gevraagd elke maand een vragenlijst in te vullen. Hierin werd gevraagd of er sprake was van recidief enkelletsel en in hoeverre de deelnemers last hadden van restklachten. Na de totale periode van twaalf maanden bleek er geen verschil in het aantal herletsel (HR 1.06: 95% CI 0.76-1.49) of de mate waarin sprake was van restklachten. We concludeerden dat wanneer een deelnemer voldoende therapietrouw is aangaande het programma, het gebruik van zowel het boekje als de App het risico op enkelblessures aanzienlijk kan verkleinen. Dit geldt voor zowel de korte als de lange termijn.

Hoofdstuk 6 – Welk programma laat een grotere kosteneffectiviteit zien?

De primaire uitkomstmaten van hoofdstuk 6 waren het aantal herletsel per 1000 uren sport en de incremental cost-effectiveness ratio (ICER) gedurende de 12 maanden waarin de deelnemers werden gevolgd. Tijdens de opvolging kregen 31 atleten te maken met herletsel waarbij er sprake was van gemaakte kosten. Dit resulteerde in een relatief risico op herletsel van 1.13 (95% CI: 0.56-2.27). De ICER van de Appgroep in vergelijking met de groep die het boekje gebruikte was −€361,52. Het kosten-effectiviteitsvlak, gepresenteerd in hoofdstuk 6, laat zien dat er geen verschil in effectiviteit of in kosten bestaat tussen beide interventiémethodes.

Hoofdstuk 7 – Wat vonden de gebruikers van de interventie?

Met behulp van het RE-AIM kader trachten we te bepalen wat de deelnemers aan het onderzoek van de interventie vonden. We keken met name naar de implementatie- en behoudsfase om de barrières en bevorderende factoren in kaart te brengen zoals die werden ervaren door de gebruikers. Semigestureerde en online vragenlijsten lieten zien dat er geen verschil bestond in ervaren gebruiksgemak, nut en plezier van de oefeningen gedurende de acht weken dat het programma duurde. Veertien van de zestien deelnemers die werden geïnterviewd zagen een toegevoegde waarde van de App ten opzichte van het boekje. Na twaalf maanden, wanneer hen gevraagd werd naar de totale
evaluatie van hun gebruikte interventiemethode, gaven de gebruikers van de App een gemiddelde (±SD) score van 7.7±0.99 in vergelijking met een 7.1±1.23 met de gebruikers van het boekje. Het verschil is score is significant (p=0.006).

CONCLUSIE

We kunnen concluderen dat de methode waarop het 'Versterk je Enkel' oefenprogramma wordt geïmplementeerd niet leidt tot een verschil in therapietrouw of in (kosten)effectiviteit. Dit geldt voor zowel de duur van het programma zelf (8 weken) als tijdens een langere periode van 12 maanden. Zowel op de korte als de lange termijn laten beide methoden evenveel recidieve enkelletsels zien. De semigestructureerde interviews en de analyses van therapietrouw en kosteneffectiviteit duiden erop dat er niet gesproken kan worden over DE (geblesseerde) atleet met vastomlijnde gedragsdeterminanten. Elk van de 220 betrokken deelnemers kwam met zijn eigen verhaal over hoe zijn blessure is ontstaan, hoe deze werd behandeld en hoe het individu zichzelf in staat achte herletsel te voorkomen. Zowel tijdens de korte als de lange termijn moesten alle deelnemers de tijd, motivatie en middelen vinden om het oefenprogramma te volgen. Sommigen slaagden hierin, anderen niet en weer enkelen slechts in beperkte mate. Het werd ons duidelijk dat niet alle deelnemers automatisch een voorkeur toonden voor het gebruik van de App. Het geprinte boekje bleek voor sommige atleten voorkeur te hebben. Traditionele implementatiemethoden hebben dus bestaansrecht naast de nieuwe, innovatieve mobiele mogelijkheden. Door het bestaan van keuze-opties worden ook de individuele voorkeur en mogelijkheden van de betrokkenen erkend. Ons advies voor personen met enkelletsel en betrokken partners is dat er ruimte moet zijn voor persoonlijke voorkeuren. Dit kan zijn het gebruik van de App, gebruik van het boekje of een combinatie van beide. Op die manier kan de atleet zelf kiezen welke methode van implementatie, op welk moment de voorkeur geniet. Onze belangrijkste boodschap is dat het programma effectief is, maar wel uitgevoerd moet worden.
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OVER DE AUTEUR